

DETERMINANTS OF NUTRITIONAL OUTCOMES AND CHALLENGES OF NUTRITIONAL PROGRAMS IN HIV CARE

IN TIGRAY REGION, ETHIOPIA:

A MIXED METHODS STUDY

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Fisaha Tesfay

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Southgate Institute for Health, Society and Equity

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SUMMARY

Background: Undernutrition and HIV/AIDS are strongly inter-related and highly prevalent in many parts of the world particularly in sub-Saharan Africa. To tackle undernutrition among people living with HIV, many countries including Ethiopia integrated nutritional programs into their HIV care services, with nutritional assessment, counselling and food supplement as key program elements. Despite some research on the effectiveness of such programs, proper evaluation of nutritional programs in the context of the Ethiopian health system is lacking. Little evidence exists about the determinants of nutritional outcomes of people living with HIV in the nutritional program or barriers and facilitators of program utilisation. Using socioecological and social determinants of health models, this study aimed to examine factors influencing the success or failure of the nutritional program in HIV care settings in Ethiopia.

Methods: The study used mixed methods involving quantitative and qualitative elements. The quantitative element of the study included a retrospective cohort study involving HIV patient records from 1757 adults and 236 children from three purposively selected hospitals in Tigray region, Ethiopia. The nutritional outcomes analysed were:

- a) **Incompleteness** (failure to stay in the program for three to six months depending on the nutritional status);
- b) **Non-response** (failure to achieve target BMI>18.5kg/m² among those completing the program and
- c) **Relapse** of undernutrition after program completion and nutritional recovery.

Logistic and Cox regression analysis were employed to identify the independent predictors of these outcomes including demographic and socioeconomic, clinical and immunological, nutritional and anthropometric factors. In the qualitative inquiry, a total of 48 in-depth interviews were conducted with adults living with HIV (n=20), caregivers of children living with HIV (n=15), health providers (n=11) and program managers (n=2). Data were analysed using a framework approach guided by the socioecological model.

Results: Rates of program incompleteness and non-response in adults were 18% and 20% respectively, while program incompleteness and non-response in children were each 14%. Among those who achieved nutritional recovery, 18% of adults and 7% of children relapsed to undernutrition. The average time to relapse of adults living with HIV to the nutritional program was 68.5 months (95% CI, 67.0–69.9). Urban residence (AOR=1.4, p≤0.02), attending the nutritional program in Shul (AOR=4.6, p≤0.0001) and Lemlem Karl (AOR=2.5, p≤0.0001) were independent predictors of nutritional program incompleteness. Similarly, urban residence (AOR= 1.46, p≤0.03), attending the nutritional program in Shul hospital (AOR=2.92, p≤<0.0001) and Lemlem Karl

(AOR=1.49, p \leq 0.047) hospitals were associated with non-response to the nutritional program. Being employed and working was associated with nutritional program incompleteness (AOR=1.39, p \leq 0.046) and frequency of relapsing (AOR=3.86, p \leq 0.029).

Lower educational status (attending primary (AOR=3.68, p≤0.03) and secondary education (AOR=3.25, p≤0.049)) and not being a member of a community support group (AOR= 1.78, p≤0.001) were independent predictors of relapse of undernutrition. Adults in the WHO classification of lower clinical stages II (AOR=2.49, p≤0.001) and III (AOR=1.46, p≤0.037) and presence of anaemia at baseline (AOR=1.77, p≤0.001) were associated with program incompleteness. Patients with advanced (WHO clinical stage IV) (AOR,0.52, p≤0.047) ≤ and bedridden functional status (AOR=0.36, p≤0.02) were more likely to recover in the nutritional program. Staying more than 24 months on ART (AOR=2.15, p≤0.004 and presence of opportunistic infections (AOR=1.68, p≤0.004) were the clinical predictors of relapse to undernutrition in adults. Children with opportunistic infections at enrolment were more likely to become non-respondent than their counter parts (AOR=8.18, p≤0.006. Severe acute undernutrition at enrolment was associated with program incompleteness in both adults and children (AOR=13.71, p≤0.024), and non-response (AOR=4.25, p<0.0001) and frequency of relapse of undernutrition (AOR=9.90, p≤0.004) only in adults.

The findings from the qualitative study revealed that knowledge of nutrition and the nutritional program, ongoing motivation to maintain the program, nutritional counselling and experience in the health service were key factors facilitating program utilisation. Experience of the nutritional support, health system related factors such as poor access, poor management and implementation of the program were reported as key barriers to the utilisation of the nutritional program. Broader sociocultural factors such as food insecurity, poverty and poor livelihood, cultural meaning of food, religious fasting, stigma and discrimination were critical challenges in program utilisation and its effectiveness in meeting the key objectives of improved nutritional status and HIV condition.

Conclusion and recommendations: A range of factors at the individual, community, health system and broader contextual levels interacted and influenced the effectiveness of the nutritional program. High rates of program incompleteness, non-response and relapse were apparent. These outcomes were associated with demographic and socioeconomic, clinical and immunological, nutritional and anthropometric characteristics of patients. Broader sociocultural factors were underlying determinants that constrained the optimal access to, and utilisation of the nutritional program in Ethiopia. The current medically-oriented strategies with an emphasis on nutritional supplements failed to address these underlying causes of undernutrition and were unable to assist patients living with HIV in maintaining nutritional wellbeing beyond the life of the program. This study concludes that individual and broader sociocultural and contextual factors are crucial considerations for nutrition program planning, implementation and evaluation, if these

programs are to be successful in reaching their goals of improving health and wellbeing for people living with HIV. To improve the nutritional outcome of patients enrolled in the nutritional program:

- Nutritional programs need to have more emphasis on women and individuals living in urban areas during enrolment, patient monitoring and follow up.
- the location of health services requires special attention to improve access to the nutritional program
- NGOs in Ethiopia needs to work more in relation to the local and national Ethiopian health priorities and health system issues while focusing on local capacity building
- Graduation criteria should take into account long term household food security, not just the
 acute treatment of undernutrition

Keywords: Ethiopia, Tigray, Mixed methods, HIV and Nutrition, Nutritional programs, Adults living with HIV, Stigma, Food insecurity.

DECLARATION

I certify that this thesis does not incorporate without acknowledgment any material previously

submitted for a degree or diploma in any university; and that to the best of my knowledge and belief

it does not contain any material previously published or written by another person except where

due reference is made in the text.

Signed: Fisaha Tesfay

Date: 19/08/2019

VII

DEDICATION

I dedicate this work to my father-Keshi Haile Tesfay and my mother-Nigisti Aregay who taught me dedication and perseverance.

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LIST OF ACRONYMS AND ABBREVIATIONS

AID: Aquired Immunodeficieny Syndrom

ART: Antiretroviral Therapy **AOR**: Adjusted Odds Ratio

AUD: Australian Dollar
BSc: Bachelor of Science
BMI: Body Mass Index

CD4: Cluster of Differentiation 4

CI: Confidence IntervalCOR: Crude Odds RatioCSB: Corn Soy Blended

CTC: Community Based Therapeutic Care

ERC: Ethical Review Committee

EDHS: Ethiopian Demographic and Health

Survey

FBF: Fortified Blended Foods

FBP: Food by Prescription Program

FGD: Focus Group Discussion

g: Gram

HBM: Health Belief Model

HFIAS: Household Food Insecurity Access

Scale

HIV: Human Immuno-deficiency Virus **HQOL**: Health Related Quality Life **IMB**: Information. Motivation and

Behavioural Skills Model

Kg: Kilograms **Kms**: Kilometre **Kcal**: Kilocalorie

Lts: Litters

MAM: Moderate Acute Malnutrition

MUAC: Mid Upper Arm Circumference

MCH: Maternal and Child Health

MNs: Micronutrients

MRN: Medical Registration Number

NACS: Nutritional Assessment, Counselling

and Support

NCHS: National Centre for Health Statistics

NGO: Non-governmental Organisations

NNP: National Nutritional Program

OCHA: United Nation Office for

Humanitarian Affairs

OVC: Orphans and Vulnerable Children **PEPFAR**: President's Emergency for AIDs

relief.

PITC: Provider Initiated HIV Testing and

Counselling

PLWA: People Living With HIV/AIDS **PHCU**: Primary Health Care Unit

PhD: Doctor of Philosophy

PMTCT: Prevention of Mother-to-Child

Transmission

RUTF: Ready to Use Therapeutic Food **RUSF**: Ready to Use Supplementary Food

SAM: Sever Acute Malnutrition

SBREC: Social and Behavioural Research

Ethics Committee

SDH: Social Determinants of Health

SEM: Socioecological Model

TB: Tuberculosis

TRHB: Tigray Regional Health Bureau

UNAIDS: Joint United Nations Program on

HIV/AIDS

QOL: Quality of Life **W/A**: Weight for Age

WFP: World Food Program

W/H: Weigh for Height **W/L**: Weight for Length

WHO: Wold Health Organization

GLOSSARY

ART: The group of drugs used to treat HIV by preventing replication of the HIV virus.

AIDS: A group of diseases or syndromes that develop in a person infected with HIV following

immunosuppression.

AIDS defining illnesses: Certain serious and life-threatening diseases that occur in HIV-positive

people are and associated with AIDS.

Body mass index: A measure of body fat calculated by dividing an individual's weight by their

height squared. It is used as a screening tool and standardized cut-off points can vary according

to ethnicity and country. In nutritional programs in HIV care, BMI is most often used in adults but

not in pregnant mothers. Although BMI can provide information about children between 2 and 17

years, it is used as widely as in adults because children have to be measured for height on each

occasion, and the measurement must be applied to the child and teen BMI calculator which takes

into account body fat changes that occur with age and differences between boys and girls referred

as "BMI-for-age".

Censored: When information about a patient's survival time is incomplete. For example, patients

are followed in a study for 20 weeks. A patient who does not experience the event of interest over

the duration of the study is said to be right censored

CD4 count: The cluster deferential which shows the immunological condition and the severity of

illness of an HIV patient. The lower the CD4 count, the worse the HIV condition.

Immune system: The second line defence mechanisms of the body which fight bacteria, virus,

fungal diseases and other parasites.

Mid-upper arm circumference: The measurement of the circumference of the mid-upper arm.

measured at the mid-point between the tip of the shoulder and the tip of the elbow, taken with the

arm hanging down. MUAC is mainly measured in children aged 6 to 59 months, and pregnant

women. It is more often used as a screening tool (for groups of people) rather than for monitoring

individual progress. A MUAC measurement tape is needed. Training of staff is required; coloured

tapes can be used by staff with less skill. Cut-off values may be population specific.

Clinically malnourished: BMI below 18.5 kg/m²

Mild to moderate malnutrition: BMI of 16.0 kg/m² to 18.5 kg/m²

Acute severe malnutrition: BMI below 16 kg/m²

XIII

Nutrition: The science of food and how it is used by our bodies to grow, work, play, maintain health and resist disease.

Opportunistic infection: Viruses, bacteria, fungi and parasites which do not usually cause disease but become pathogenic in a person with compromised immune system because of HIV and other illness.

Pre-ART: People who do not start ART because of non-eligibility despite their positive HIV status.

Sachet: Packaging for the nutritional support, which is usually Plumpynut/Sup or other types of food.

Stunting: Compared with wasting (or acute undernutrition), which can develop over a short period and is reversible, the development of stunting is a gradual and cumulative process during the first 1,000 days from conception through the first two years of a child's life. Stunting develops as a result of sustained poor dietary intake or repeated infections or a combination of both. It has severe, irreversible consequences, beyond the short stature of the individual.

Tertile: Any of the two points that divide an ordered distribution into three parts, each containing one third of the population.

Underweight: Low weight-for-age measurement calculated by on comparing the weight-for-age of a child with the WHO international growth reference standard. Underweight reflects both stunting and wasting.

Undernutrition: includes wasting (low weight-for-height), stunting (low height-for-age) and underweight (low weight-for-age).

Wasting: Acute undernutrition, or wasting, develops as a result of recent rapid weight loss or a failure to gain weight. In children, it is assessed by low weight-for-height or mid upper arm circumference (MUAC). The degree of acute undernutrition is classified as acute moderate or severe. Wasting is often used to assess the severity of an emergency because it is caused by illness and/or sudden severe lack of food and is strongly related to mortality status. The indicator for stunting is low height-for-age, a measurement that is calculated by comparing the height of a child against the WHO international growth reference standard for a child of the same age.

OPERATIONAL DEFINITIONS

Adults living with HIV: HIV patients who were 18 years of age and older. Adults living with HIV

will be referred as "adults" across this PhD thesis.

Baseline information: Information collected (taken) before or during enrolment to the nutritional

program.

Caregivers of children with HIV: Attendants a child with HIV at the time of data collection. They

could be biological or non-biological parents of the child but are involved in the care and support of

the child.

Children living with HIV: HIV patients who are under 18 years of age. Children living with HIV will

be referred to as "children" across this PhD thesis.

Defaulters: Patients/caregivers who missed the nutritional program for two consecutive months.

Graduated (recovery): Patient that has reached the discharge criteria (BMI, MUAC, and W/H -Z

score or W/H % of median) and has been removed from the program. (Note: This terminology is

used widely in general nutrition programs. However, in the HIV setting, it is recommended that the

word "recovered" may be more appropriate given the incurable nature of the underlying disease).

Health providers: Individuals working in the HIV care providing HIV related services including the

nutritional program in hospitals when interviewed.

Index/Primary person: Refers to the primary beneficiary of the nutritional program.

Immune recovery: Refers to improvements in CD4 count.

Improved nutritional status: Indicates an increase in body mass index or mid upper arm

circumference.

Logbook: The registration book used to monitor and follow nutritional status of people living with

HIV in the nutritional program.

Malnutrition: Also used to refer to undernutrition.

Nutritional program: The nutritional program includes all the nutritional activities carried out with

HIV positive patients or patients on ART such as nutritional assessment, categorization, nutritional

counselling, provision of the Plumpynut/Sup and follow up of nutritional status, which takes different

forms based on the context.

ΧV

Nutritional support: Refers to the food given to malnourished HIV patients identified as Plumpynut or Plumpysup as a trade mark or refers to macronutrient supplementation.

Plumpynut. Study participants used Plumpynut when referring to the nutritional program in general.

Drug regulatory task force: A group of people from different sectors such as police, health authority, and respective government authorities established to control and regulate drugs.

Utilisation: Patients who are enrolled in the nutritional program who undergo assessment, receive the necessary counselling, and use the nutritional support for the recommended period (3–6 months). Thus, utilisation includes all components of the nutritional program mentioned earlier.

Well nourished: Refers for those individuals who were not diagnosed as undernourished.

CONFERENCE PRESENTATIONS

- Fisaha Haile Tesfay, Sara Javanparast, Anna Ziersch, Lillian Mwanri, Afework Mulugeta: Stigma and discrimination: A barrier to the utilization of nutritional care services in HIV care in Ethiopia. (SA population health conference 2017, October 21/2017, Adelaide South Australia), Oral presentation.
- 2. Fisaha Haile Tesfay, Sara Javanparast, Anna Ziersch, Lillian Mwanri2, Afework Mulugeta: Experience of nutritional counselling in nutritional program in HIV care in Ethiopia, Exploration of policy-practice gap: (Australian Society for Medical Research, South Australian Scientific Meeting 6-8th June 2018, Adelaide South Australia), Poster presentation.
- 3. Fisaha Haile Tesfay, Sara Javanparast, Anna Ziersch, Lillian Mwanri, Afework Mulugeta: Contextual determinants influencing the utilization of nutritional program among adult patients with HIV in Ethiopia: A mixed methods study (4th International Conference on Public Health, 19th –21 July 2018, Bangkok, Thailand), Oral presentation. (Awarded the best session presentation).
- Fisaha Tesfay^{1,2}, Sara Javanparast, Anna Ziersch, Lillian Mwanri, Afework Mulugeta: Food insecurity and nutritional programs in HIV care service, a qualitative analysis of impeding challenges in Ethiopia. (21st November 2018, ASMR 2018 National Scientific Conference), Oral presentation.

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CHAPTER 1: INTRODUCTION

1.1 Global and regional picture of HIV and AIDS

In 2017, 36.9 million people were living with HIV globally and 2.1 million of these were children (<u>UNAIDS 2018a</u>). New Human Immune Deficiency Virus (HIV) infections and deaths due to Acquired Immune Deficiency Syndrome (AIDS) related causes were 1.8 and 1 million respectively (<u>UNAIDS 2018a</u>). From 2000 to 2016/2017, the number of people living with HIV has increased probably due to improved survival rates for people living with HIV. Improved survival may be due to the improved care and access to antiretroviral therapy (ART). During the same time period, the number of AIDS related deaths and new infections decreased from 1.5 million to 1 million (**Figure 1.1**). Access to ART grew exponentially from 2010 to 2017 and has continued to increase (**Figure 1.1**).

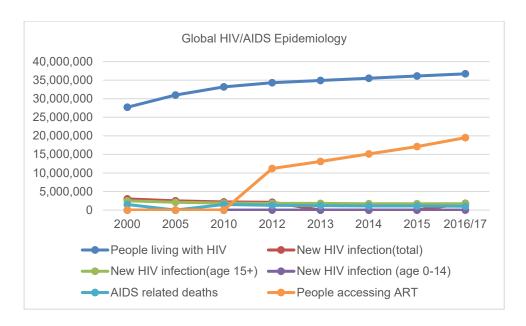


Figure 1.1: Global epidemiology of HIV/AIDS, Source (UNAIDS 2018a).

Sub-Saharan Africa is disproportionately affected by the epidemic of HIV and AIDS. Of 6000 new infections that occur worldwide daily, two out of three are in sub-Saharan Africa (Kharsany and Karim 2016). Furthermore, 59% of new HIV infections that occur in sub-Saharan Africa are among women (UNAIDS 2018a). Young women aged 15-24 years have eight times higher rates of HIV infection than males in sub-Saharan Africa (Kharsany and Karim 2016). Various biological, behavioural, socioeconomic and structural factors such as gender inequality, sexual violence and HIV related stigma increase the vulnerability of women to HIV in sub-Saharan Africa (Ramjee and Daniels 2013).

The magnitude of HIV and AIDS in Africa varies but eastern and southern Africa have been hardest hit by the epidemic (<u>African Commission On Human and Peoples' Rights 2017</u>). In eastern and southern Africa, 19.4 million people live with HIV, which is 52.5% of the global total (<u>UNAIDS 2018a</u>) (**Table 1.1**). Nearly, 6.2% of the global population live in eastern and southern Africa but half of all people living with HIV live there (<u>Lynsey 2017</u>). Furthermore, because of their high vulnerability to HIV infection possibly due high sexual activity, limited knowledge of HIV transmission and some of them born with HIV, young people (10-24 years of age) in eastern and southern Africa are most affected by the epidemic (<u>Lynsey 2017</u>).

Table 1.1: Regional epidemiology of HIV and AIDS in 2016.

WHO Region	Adults and children living with HIV	Adults and children newly infected	Adult and child AIDS deaths
Eastern and southern Africa	19.4 million	790,000	420,000
Western and central Africa	6.1 million	370,000	310,000
Asia and the Pacific	5.1 million	270,000	170,000
Latin America	1.8 million	97, 000	36, 000
The Caribbean	310, 000	18,000	9,400
Western and central Europe and north America	2.3 million	73,000	18, 000
Eastern Europe and central Asia	1.6 million	190,000	40,000
Middle east and north Africa	230,000	18,000	11,000

Source (UNAIDS 2018a).

In eastern and southern Africa, 83% of new HIV infections were in the general population, followed by 8% and 6% amongst clients of sex workers and other clients (<u>UNAIDS 2018b</u>).

HIV remains the major killer in sub-Saharan Africa and accounts for 20% of all deaths (<u>Pribram 2010</u>). In 2017 in sub-Saharan Africa, mortality due to AIDS related causes was 420,000 and the total number of AIDS deaths in eastern and southern Africa was estimated to be 380, 000 (<u>UNAIDS 2018a</u>).

1.2 Overview of health system and HIV in Ethiopia

This study was conducted in Ethiopia with the aim of examining challenges in the nutritional program in HIV care. Located in the Horn of Africa (Figure 1.2), Ethiopia is the second-most populous country in sub-Saharan Africa after Nigeria, with a total population of more than 96,000,000 (as of July 2018) and a population growth rate of 2.6% per year (Ethiopian Centeral Statistical Agency 2007). Under the 1994 constitution, Ethiopia is administratively structured into nine regional states: Tigray, Afar, Amhara, Oromiya, Somali, Benishangul-Gumuz, Southern Nations Nationalities and Peoples (SNNP), Gambela and Harari; and two city council administrations which include Addis Ababa and Dire Dawa (Figure 1.2) (The Federal Democratic Republic of Ethiopia 1995).

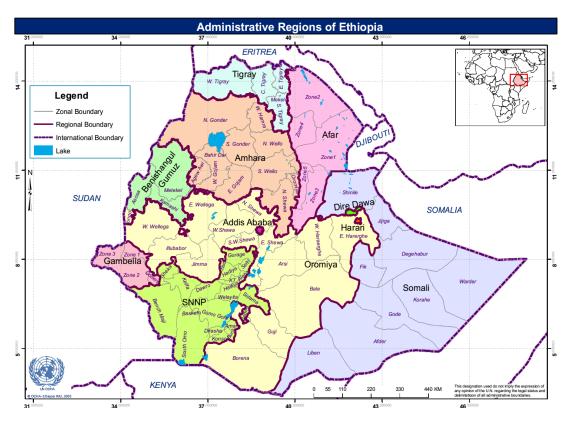


Figure 1.2: Map of Ethiopia with the administrative regions (**Source**: United Nations office for coordination of humanitarian affairs).

The major health challenges in Ethiopia include HIV and AIDS, tuberculosis, malaria and nutritional disorders, along with chronic non-communicable diseases such as cardiovascular disease, diabetes mellitus, chronic respiratory disease and injuries (Federal Ministry of Health of Ethiopia 2010; Misganaw et al. 2014). Ethiopia is one of the sub-Saharan African countries significantly affected by the epidemic of HIV and AIDS. In 2017, the total number of people living with HIV in Ethiopia was 722,248 including 57,132 children with an annual death rate of 2,607 (Ethiopian Public Health Institute 2017). In Ethiopia, the prevalence of HIV is currently 0.9% with significant reduction in the prevalence of HIV from 4.4% in 2000 to 0.9% in 2016 (Nagata et al. 2014) (Figure 1.3).

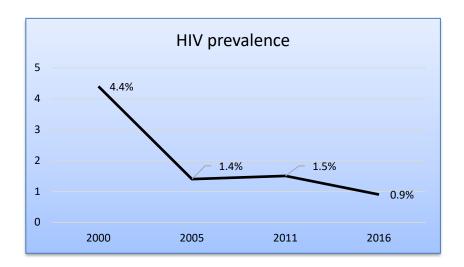


Figure 1.3: Trend of HIV prevalence in Ethiopia 2000 to 2016 (sources: Ethiopian demographic and health surveys 2000-2016).

According to the Ethiopian Demographic and Health Survey (EDHS) 2016, the adult HIV prevalence in Ethiopia among men and women aged 15-49 varies considerably by age and sex, with the highest prevalence occurring between ages 30 to 49 years, and higher rates in most age groups for women, mirroring broader patterns across Africa (**Figure 1.4**).

Percentage of women and men who are HIV positive 3.5 3.0 2.5 2.0 1.5 1.0 0.5 0.0 15-19 20-24 25-29 30-34 35-39 40-44 45-49 50-54 55-59 Age in years

Figure 1.4: Age and sex distribution of HIV prevalence in Ethiopia (<u>Central Statistics Agency (CSA)</u> <u>Ethiopia and ICF 2016</u>).

Regarding the regional distribution of HIV in Ethiopia, the highest prevalence of HIV is reported in Gambela (4.8%) and Addis Ababa (3.4%) (**Figure 1.5**) (Central Statistics Agency (CSA) Ethiopia and ICF 2016).

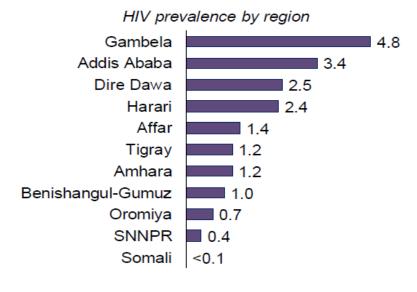


Figure 1.5: HIV prevalence by region in Ethiopia (<u>Central Statistics Agency (CSA) Ethiopia and ICF 2016</u>).

This particular study was conducted in the Tigray region of Ethiopia were the prevalence of HIV was 1.2% with a total of 59,583 people living with HIV in the year 2016 (Central Statistics Agency (CSA) Ethiopia and ICF 2016) and predicted prevalence of 1.7% for the year 2018 (Ethiopian Public Health Institute 2017). The prevalence of HIV across the different administrative zones within Tigray was variable ranging from 2.2% in the Western zone to 0.4% in the Central zone (Figure 1.6) (Barnabas et al. 2014) but there is no recent estimate on the zonal distribution of HIV in the Tigray region. The prevalence of HIV among commercial sex workers in Mekelle, the capital city of Tigray region was 33% which is the highest of all regional capital cities in Ethiopia (Federal HIV Prevention and Control Office of Ethiopian 2014) and the overall regional prevalence among this group ranges from 10% to 20% (Barnabas et al. 2014). The high prevalence of HIV makes the Tigray region of Ethiopia a particularly important site for this study.

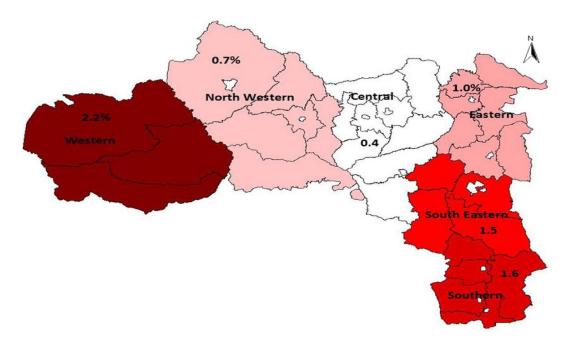


Figure 1.6: Distribution of HIV by zone in Tigray region, Ethiopia (Barnabas et al. 2014).

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¹ Zone is a third level administrative structure in Ethiopia.

To respond to these health challenges, the Ethiopian health care delivery system is organised into three-tiers or levels (**Figure 1.7**). Level one is the *woreda*/district health system comprised of a primary hospital (which delivers curative and preventive services to a population of 60,000–100,000), health centres (with one health centre expected to serve 15,000–25,000 people) and their satellite health posts (expected to serve 3,000–5,000 people). The primary hospital, health centre and satellite health posts are connected to each other by a referral system and together form a Primary Health Care Unit (PHCU). The second tier of the health system is a general zonal hospital which is expected to serve a population of 1–1.5 million, and the third level of care is a specialised national or regional referral hospital which serves a population of 3.5–5 million people (<u>Federal Ministry of Health of Ethiopia 2010</u>). Government (31%) and other public enterprises and donor organisations (37%) are the major sources of finance for the Ethiopian health system (<u>Ali 2014</u>; <u>Wamai 2004</u>, <u>2009</u>).

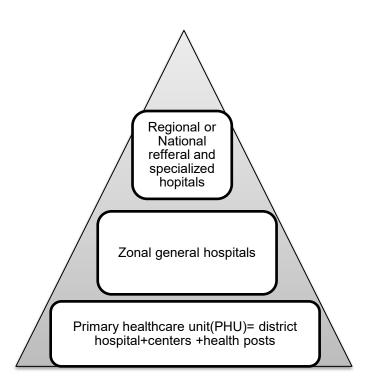


Figure 1.7: Organisation of health care delivery in Ethiopia.

1.3 HIV and undernutrition

Undernutrition contributes to 11% of the global burden of disease in general (Kerac et al. 2009). Undernutrition is also an important public health problem among people living with HIV in resource poor settings (Koethe and Heimburger 2010; Obi, Ifebunandu and Onyebuchi 2010). Undernutrition among children living with HIV is also widespread and higher in magnitude than among adults living with HIV in sub-Saharan Africa (Alebel et al. 2018; Jesson et al. 2015; Penda et al. 2018) (A detailed review of the magnitude of undernutrition in adults and children is found in chapter 2 section 2.3.2). The high magnitude of HIV morbidity and mortality in sub-Sharan Africa is closely linked to undernutrition and food insecurity (Anabwani and Navariob 2005).

A complex relationship exists between undernutrition and HIV infection (Salomon, De Truchis and Melchior 2002). Undernutrition and AIDS are strongly inter-related and act synergistically in patients infected with HIV. Both weaken the immune system and have a major impact on disease progression, clinical outcomes and quality of life (Davidhizar and Dunn 1998). Undernutrition can amplify the effect of HIV on the immune system by increasing susceptibility to AIDS related opportunistic infections (Salomon, De Truchis and Melchior 2002). HIV and AIDS is known for its contribution to weight loss among people living with HIV which is defined as involuntary weight loss of more than 10% (Anabwani and Navariob 2005; Malvy et al. 2001). For instance, during the early periods of the Epidemics of HIV and AIDS, widespread undernutrition known as "slim disease" was common (Anabwani and Navariob 2005). On the other hand, both symptomatic and asymptomatic HIV infections increase energy requirements (PEPFAR 2006). For example, the daily energy requirement of people living with HIV and AIDS is 30% higher than in non-HIV infected individuals of the same age, sex and level of physical activity (WHO 2003a).

In areas of endemic undernutrition, factors such as HIV and other communicable diseases that increase susceptibility to undernutrition are common (Anabwani and Navariob 2005). Areas with high levels of HIV or AIDS are also affected by food insecurity and undernutrition because of the decline in overall household socioeconomic status, resulting from loss of productivity, costs of accessing health services and school dropout because of ill health and stigma (PEPFAR 2006). The impacts of HIV and AIDS on nutritional status or vice versa is not limited to the individual but also has enormous effects on families and communities (PEPFAR 2006). For example, HIV and AIDS can contribute to loss of employment in farming and other household activities, increase the health service expenditure, and reduce capacity to support children, and other vulnerable family members (Panagides et al. 2007). Similarly, undernutrition also increases susceptibility to HIV and AIDS because of food insecurity and poverty (Gillespie, Haddad and Jackson 2001).

Globally, the highest level of undernutrition (22.7%) occurs in sub-Saharan Africa and similarly, sub-Saharan Africa is the region worst affected by the double burden of undernutrition and HIV and AIDS globally (PEPFAR 2006). One of the most common forms of undernutrition in sub-Saharan Africa is protein—energy undernutrition, which contributes to AIDS mortality by enhancing immunosuppression among people living with HIV (Koethe and Heimburger 2010). Generally, undernutrition and HIV in sub-Saharan Africa are syndemic conditions (Ivers et al. 2009).

The overlap of undernutrition, HIV and AIDS in eastern and southern Africa exceeds that seen in sub-Saharan Africa. Undernutrition in eastern Africa is highest (33.9%) in sub-Saharan Africa (<u>FAO</u> et al. 2017) and the numbers of people living with HIV, new HIV infections and AIDS related deaths are also the highest in eastern and southern Africa as described in **Table 1.1**.

Considering the interaction and large extent of undernutrition among adults and children living with HIV or AIDS, the integration of nutritional programs into HIV care was recommended by the World Health Organization (WHO) and other international and national organizations (Aberman et al. 2014; WHO 2003a, 2005). The WHO argued that nutritional care and support was one of the most immediate and critical interventions for people living with HIV (WHO 2005). In addition, nutritional care and support has been demonstrated in many studies in sub-Saharan Africa as leading to improvements in nutritional status, ART adherence and clinical outcomes for people living with HIV (Cantrell et al. 2008; Lategan, Steenkamp and Joubert 2010; Sadler et al. 2012).

Food and nutrition has been integrated into global AIDS policy since 2006 and programs targeting food insecurity and nutritional care for people living with HIV or AIDS have been in place in sub-Saharan Africa since then (<u>Aberman et al. 2014</u>). Thus, nutritional interventions remain key to HIV treatment, care and support services in sub-Saharan Africa (<u>Koethe and Heimburger 2010</u>). To maintain the immune system and sustain healthy levels of wellbeing among people living with HIV, nutritional assessment, counselling and support is an integral part of a comprehensive response to HIV and AIDS (<u>Aberman et al. 2014</u>; <u>Audain et al. 2015</u>).

Different nutritional interventions have been used in different settings and countries to improve nutritional status and other clinical outcomes for people living with HIV (<u>Grobler et al. 2013</u>; <u>Mahlungulu et al. 2007</u>). Nutritional care and support services to people living with HIV has ranged from nutritional counselling only to the provision of micronutrient, macronutrient or fortified macronutrient supplementation (<u>Anema et al. 2012</u>; <u>Mahlungulu et al. 2007</u>).

Nutritional programs in HIV care settings in sub-Saharan Africa vary depending on the donor organisation and availability of other resources (<u>Greenaway 2009</u>). Nutritional programs involving nutritional assessment, counselling and support have been one of the most common nutritional programs in eastern and southern Africa (<u>Food and Nutrition Technical Assistance II Project (FANTA-2) 2009</u>; <u>Sadler et al. 2012</u>). For instance, in eastern and southern Africa the food by prescription program (FBP) which views food as medicine was implemented to fight undernutrition among people living with HIV and later this was extended to include nutritional assessment, counselling and support (<u>Aberman et al. 2014</u>). Provision of therapeutic or supplementary foods to treat undernutrition among people living with HIV who receive care for chronic HIV has been widely used in HIV treatment, care and support programs in low resource settings including Ethiopia (<u>Government of the Federal Democratic Republic of Ethiopia 2013–2015</u>; <u>Ivers et al. 2009</u>; <u>Manary, Trehan and Willumsen 2012</u>; <u>van Oosterhout et al. 2010</u>).

1.4 Description of the nutritional program in HIV care in Ethiopia

Since 2008, the Ethiopian Federal Ministry of Health has incorporated nutritional care and support as an essential component of HIV care to maintain the nutritional status of people living with HIV in Ethiopia (Federal Ministry of Health of Ethiopia 2008a). The national nutritional strategy and guidelines for clinical nutritional care for people living with HIV were also developed into the same year following the incorporation of nutrition in HIV care (Federal Ministry of Health of Ethiopia 2008a, 2008c).

The nutritional program in HIV care commenced in 2010 in Ethiopia and involves nutritional assessment, counselling and support (NACS) for undernourished people living with HIV. The 2013–2015 National Nutritional Program (NNP) in Ethiopia emphasised the sustained integration of NACS into HIV treatment, care and support services (Government of the Federal Democratic Republic of Ethiopia 2013–2015). The nutritional support component of the nutritional program provides Ready to Use Supplementary Food (RUTF), a Plumpynut® paste for severe acute undernutrition and Plumpy'Sup® paste for moderate acute undernutrition, to reverse undernutrition among people living with HIV (Anthony and Jayashankar 2009; Sadler et al. 2012). The criteria for provision of nutritional support are based on objective physical measurement such as Body Mass Index (BMI) in adults and mid-upper arm circumference (MUAC), Weight for Height–Z scores (W/H–Z) or Weight for Height percentages (W/H%) median in children (Federal Ministry of Health of Ethiopia 2008a; Sadler et al. 2012).

The program includes nutritional assessment, counselling and the provision of food/nutrition services at clinical settings as part of HIV treatment and care. All people living with HIV and enrolled in chronic HIV care are screened regularly for undernutrition during their follow-up visits or ART appointments using objective anthropometric entry and exit criteria. Individuals are given prescription of a therapeutic or supplementary food to take home, with the aim of rehabilitating their nutritional status and improving health. Health facility staff collect demographic and socioeconomic, immunological and clinical, nutritional and anthropometric data, and closely monitor people living with HIV enrolled in the nutritional program during monthly appointments. After enrolment in the nutritional program, renewal of prescription for the food is done during monthly follow up visits or ART medication appointments. RUTF/RUSF food rations are distributed directly from clinic pharmacies. There are differences in enrolment, exit criteria and ration size between children and adults living with HIV enrolled in the nutritional program. These differences are described below:

1.4.1 Adult nutritional outcomes

An adult person enrolled in the nutritional program can have one of the following outcomes:

Recovered: Participant reached a BMI of 18.5kg/m² for two consecutive visits within three months for moderate acute undernutrition and six months for severe acute undernutrition at baseline.

Non-response/Unrecovered: Participant did not reach a BMI of 18.5kg/m² for two consecutive visits within three months for moderate acute undernutrition or six months for severe acute undernutrition.

Program incompleteness²: Participant did not reach a BMI of 18.5kg/m² and dropped out of the program before the end of three months in moderate acute undernutrition or six months in severe acute undernutrition.

Died: Participant died during the course of program participation, and death was documented by clinic staff in the registration book.

Relapse of undernutrition after nutritional recovery: Participants returned with either moderate or severe acute undernutrition after being declared nutritionally recovered.

1.4.2 Child nutritional outcomes

Undernourished children living with HIV have a similar nutritional management protocol as HIV negative undernourished children depending on their age (Federal Ministry of Health of Ethiopia 2007; Manary, Trehan and Willumsen 2012; Tadesse, Girma and Tegegne 2010). Undernourished children without medical complications are managed as outpatients by providing RUTF/RUSF to their caregivers based on their mid upper arm circumference (MUAC), weight for height z-score (WHZ) or weight for height percentage (W/H% median) (Federal Ministry of Health of Ethiopia 2008a; WHO 2009). Thus, nutritional outcomes of children living with HIV are defined as follows:

Recovered: For children 6 months to 14.9 years, weight for length (W/L%) or W/H ≥85% on more than one occasion and absence of oedema for 10 days.

Non-response/Unrecovered: Children who do not fulfil the above recovery or discharge criteria for the duration of nutritional support, which is three months for moderate acute undernutrition and six months for severe acute undernutrition.

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² Program incompleteness includes default and lost to follow up

Default: Child dropped out of the program before meeting the criteria for recovery mentioned above.

Died: Child died during the course of program participation, and death was documented by health provider in the register book.

Relapse of malnutrition after nutritional recovery: Child returned with either severe or moderate or mild acute undernutrition after being declared nutritionally recovered and discharged from the nutritional program.

1.5 Statement of the problem

Despite the different forms of nutritional programs in HIV care settings, the overall aim of these programs is to improve the nutritional wellbeing of people living with HIV (Iverset al. 2009). However, there are demonstrable challenges for nutritional programs in HIV care settings (Ahoua et al. 2011; Nagata et al. 2014). These programs are characterized by high program incompleteness, non-response to the nutritional program and relapse of undernutrition (Ahoua et al. 2014; Sadler et al. 2012) (refer for further details in chapter 2, section 2.7). However, because of the diversity of nutritional programs employed in HIV care settings, the factors that contribute to the problems of program effectiveness vary depending on enrolment criteria, type of nutritional support, duration of the nutritional program and criteria for graduation or recovery.

Only a small number of studies have been conducted in eastern and southern Africa to evaluate nutritional programs in HIV care. Existing studies are limited to pilot studies and baseline evaluation of nutritional programs, with none conducted in a real world programmatic implementation setting (Ahoua et al. 2011; Dibari et al. 2012; Nagata et al. 2014). These studies have identified demographic and socioeconomic, immunological and clinical, nutritional and anthropometric factors but these factors may not be similar across different settings because of variations in the context and program implementation. Furthermore, evidence is lacking to inform practitioners about how nutritional programs in HIV care settings should be effectively implemented in resource-poor settings, the optimum ingredients and duration of nutritional support and factors influencing program utilisation.

A small number of studies have been conducted in Ethiopia to examine the effectiveness of nutritional programs and identify the determinants of program outcomes. Quantitatively, one study in Ethiopia found a high degree of nutritional program incompleteness (70.6%), non-response (58%) and relapse of undernutrition (20%), but the factors that contributed to ineffectiveness of the nutritional program were not compressively examined. Furthermore, it was conducted at the initial stage of the nutritional program as a pilot evaluation and not during the real program operation, and the study did not include children living with HIV (Sadler et al. 2012). Another quantitative study in Ethiopia also found low nutritional recovery and identified some demographic and socioeconomic, clinical and nutritional characteristics related to nutritional program recovery (Maldey, Haile and Shumye 2014) but did not examine the determinants of program incompleteness, non-response and relapse of undernutrition and did not involve children living with HIV. Hence, no study has assessed the broader demographic and socioeconomic, immunological and clinical, nutritional and anthropometric correlates of program incompleteness, non-response and relapse of undernutrition in Ethiopia especially in the Tigray region.

A small number of studies in Ethiopia have explored patient experiences and adherence and compliance. However, these studies only examined nutritional support elements of the program (Hussien et al. 2015; Kebede and Haidar 2014; Olsen et al. 2014). In addition, none of the studies involved diverse views from various program stakeholders to understand the challenges of the nutritional program or an examination of contextual differences and broader challenges for the nutritional programs. Furthermore, none of the above studies examined the nutritional outcomes of children living with HIV enrolled in nutritional programs. As far as is known, there have been no studies that assessed and explored caregivers' perspectives of the barriers and facilitators of use of the nutritional programs among children living with HIV.

The rationale for this PhD study is as follows:

- 1. There is a gap in the literature to guide nutritional programs in HIV care and factors that affect nutritional program effectiveness in resource-poor settings.
- 2. There is no research which has examined nutritional programs in HIV care beyond the individual level behavioural factors in Ethiopia.
- 3. Real world programmatic evidence evaluating the multifaceted challenges of nutritional programs in HIV care settings is lacking and needed to help guide future policies and programs to ensure optimal nutritional and health outcomes of people living with HIV.
- 4. Given that the Tigray region has a relatively high prevalence of HIV in Ethiopia, conducting an in-depth analysis of the nutritional program in HIV care is fundamentally crucial to improve nutritional care and support in HIV care settings in Tigray and to inform national policies in Ethiopia.
- 5. There is no study seeking the perspectives of different program stakeholders about the barriers and facilitators of utilisation of the nutritional program in HIV care settings in Ethiopia.
- 6. Evidence related to programmatic, health system and sociocultural factors challenging the nutritional program in HIV care is lacking.

This study examines the correlates of nutritional outcomes of the nutritional program by identifying broader demographic and socioeconomic, immunological and clinical, nutritional and anthropometric determinants of program incompleteness, non-response and relapse of undernutrition. It also aims to fill the knowledge gap on factors affecting nutritional outcomes among children living with HIV who are enrolled in the nutritional program. The current study involved adults, caregivers, health providers and program managers to gain an in-depth understanding of the challenges of the nutritional program in HIV care. It draws on the socioecological model to examine contextual factors and broader implementation and operational challenges of the nutritional program in HIV care settings in the Tigray region of Ethiopia. Hence, the current study aims to provide comprehensive evidence of the challenges of the nutritional program by employing both quantitative and qualitative methods and programmatic data and involving a range of stakeholders from the nutritional program in HIV care settings.

1.6 Research hypothesis, aims and objectives

1.6.1 Study aims and objectives

Overall goal:

▶ To assess determinants of nutritional outcomes and challenges of the nutritional program in HIV care in the Tigray region, Ethiopia.

Aim 1

 To describe the pattern and identify the determinants of the nutritional outcomes of adults living with HIV enrolled in the nutritional program in the Tigray region, Ethiopia.

Specific objectives

- To describe the pattern of program incompleteness, non-response, and relapse among undernourished adults living with HIV.
- To identify the demographic and socioeconomic correlates of nutritional outcomes of undernourished adults living with HIV enrolled in the nutritional program.
- To identify the baseline immunological and clinical correlates of nutritional outcomes among undernourished adults living with HIV enrolled in the nutritional program.
- To identify the baseline nutritional and anthropometric correlates of nutritional outcomes among undernourished adults living with HIV enrolled in the nutritional program.

Study hypothesis I: Program incompleteness, non-response, and relapse of undernutrition is affected by baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics among adults living with HIV

Aim 2

• To describe the pattern and determinants of the correlates of nutritional outcomes of children living with HIV enrolled in the nutritional in the Tigray region, Ethiopia.

Specific objectives

- To describe the patterns of program incompleteness, non-response and mortality and relapse
 of undernutrition among undernourished children enrolled in the nutritional program.
- To identify the demographic and socioeconomic correlates of nutritional outcomes of undernourished children living with HIV enrolled in the nutritional program.
- To identify the immunological and clinical correlates of nutrition outcomes of undernourished children living with HIV enrolled in the nutritional program.
- To identify the nutritional and anthropometric correlates of nutritional outcomes of undernourished children living with HIV enrolled in the nutritional program.

Study hypothesis II: Program incompleteness, non-response, and relapse of undernutrition is affected by baseline demographic, and socioeconomic immunological and clinical, nutritional and anthropometric characteristics among children living with HIV.

Aim 3

 To assess the barriers and facilitators of utilisation of the nutritional program in HIV care among stakeholders, in the Tigray region, Ethiopia.

Specific objectives

- To explore the adult's perspectives of barriers and facilitators of use of the nutritional program among adults living with HIV enrolled in the in the nutritional program.
- To explore caregivers' perspective of barriers and facilitators of use of the nutritional program among children living with HIV enrolled in the nutritional program.
- To explore health providers and program managers' perspectives of barriers and facilitators of use of the nutritional program among people living with HIV

1.7 Thesis structure

The thesis consists of seven Chapters. **Chapter One** provides a background and rationale for the study. **Chapter Two** reviews the available evidence about links between undernutrition and HIV or AIDS; nutritional interventions in HIV care in sub-Saharan Africa; and the impact of undernutrition on HIV mortality, survival, ART adherence and quality of life. Furthermore, challenges of nutritional programs in HIV care settings are reviewed and synthesised. The underpinning theoretical models that this thesis draws up on are also outlined in this chapter.

Chapter Three describes the study settings followed by the overall methodology underpinning the current study. Data collection procedures and methods of data analysis for the quantitative study are also described. The description of the qualitative study including the recruitment strategy for study participants is also provided. The Chapter concludes with a description of the ethical issues and appropriate ethics approvals granted.

Chapter Four presents the quantitative results and involves the analysis of demographic and socioeconomic, immunological and clinical, nutritional and anthropometric determinants of nutritional outcomes of the nutritional program. The first section describes demographic and socioeconomic, immunological and clinical characteristics and nutritional and anthropometric determinants of nutritional outcomes in adults. The second section presents these analyses for children.

Chapter Five: Presents the barriers to and facilitators of utilisation of the nutritional program in HIV care from the perspectives of program stakeholders. In **Chapter Six**, the findings are discussed in light of previous research and the theoretical models, alongside strengths and limitations of the study. Finally, the conclusions and implications of the study are presented in **Chapter Seven**.

CHAPTER 2: LITERATURE REVIEW

Introduction

This Chapter describes and appraises the current literature relevant to the study. It begins by describing the literature search strategy employed in this thesis. It then outlines the biomedical aspects of HIV and AIDS. In the subsequent sections, the literature review covers the links between HIV and AIDS and undernutrition and magnitude of undernutrition; impact of undernutrition on mortality, ART adherence and quality of life; nutritional interventions in HIV care in sub-Saharan Africa; the impact of nutritional support in improving nutritional status, survival and ART adherence; and challenges of nutritional programs in HIV care. The gaps in the literature are summarised and the chapter concludes with an appraisal of relevant theoretical models considered for the study.

2.1 Literature search strategy

A literature review is a comprehensive summary and synthesis of ideas, evidence, approaches and research findings that have been published on a certain topic of study or subject. There is no globally agreed set of distinct, coherent and mutually exclusive types of literature review (<u>Grant and Booth 2009</u>). However, the review types are grouped into three broad categories based on the purpose of review, research question, searching mechanism, screening and measures applied to control for bias. These are: a) scoping literature review; b) systematic review and meta-analysis; and c) narrative review (<u>Grant and Booth 2009</u>).

A scoping review is a descriptive overview of the literature to examine and explore the range and nature of evidence on a particular topic in studies with a large range of study designs and methodologies (Pham et al. 2014; Valaitis 2012). However, the current literature review was beyond exploratory and descriptive overview. On the other hand, systematic review and meta-analysis are scientific tools that include a process of systematic searching, selecting, appraising, synthesizing and reporting research evidence on a particular question using explicit methodology to minimise bias (Green 2005; <a href="Khan et al. 2003; Ng and Peh 2010). Given the wider spectrum of the evidence included and reviewed here, the breadth of the research questions, and the diverse nature of the quality of the evidence, a systematic review was not appropriate for the current literature review.

Narrative review was used in this literature review which is a traditional approach characterized by drawing theoretical and conceptual ideas from a range of sources (Kiteley and Stogdon 2014). It involves a broad search for quantitative and qualitative evidence from a wide range of sources and syntheses of given evidence but usually without adhering to a defined searching strategy or strict inclusion and exclusion criteria, as used in systematic review and meta-analysis (Cipriani and Geddes 2003; Collins and Fauser 2005). In this study, a narrative review of literature was used because inclusion of grey literature, reports, government and non-government documentation alongside peer reviewed literature was important. These policy and practice documents and guidelines were crucial for understanding issues around policy development and program implementation but which were not suitable for inclusion in a systematic review because of issues of quality.

Searching was undertaken using the following search engines and electronic databases: ProQuest, Scopus, Web of Science, PubMed and Science direct. Moreover, extensive searches were conducted using Google Scholar and Google search for relevant websites, grey literature, reports, theses and other relevant sources. The reference lists of the most relevant research papers and reports were also searched, retrieved and included in the literature review where appropriate. The inclusion criteria for academic literature included peer-reviewed journal articles published in English between 2005 and 2018 and limited to sub-Saharan Africa. However, searches for certain themes, such as the general link between HIV and nutrition and impact of undernutrition on quality of life, included sources from areas other than sub-Saharan Africa. The reasons for this were a) links between HIV and undernutrition are not limited to a certain geographic area; and b) there was inadequate evidence regarding the impact of undernutrition on quality of life. Other than the theme that examined the links between HIV and undernutrition, the search was limited to work published between 2005 and 2018 because many studies related to nutritional programs have been conducted since 2005 and this was when most nutritional programs were first implemented as part of HIV care in sub-Sharan Africa. Identified literature was managed using Endnote (X8) bibliographic software package.

Search terms and subject headings were developed from an initial preliminary assessment and exploration of the evidence regarding HIV and nutrition and nutritional programs in HIV care. In addition, the research question and objectives were used as sources of the search terms and subject headings. The main subject headings used were: HIV and undernutrition; undernutrition, HIV mortality, ART adherence and quality of life; nutritional interventions in sub-Saharan Africa; nutritional support, role of nutritional support in improving nutritional status, survival and ART adherence and challenges of nutritional programs in HIV care settings (**Table 2.1**). Search terms was identified from the subject headings and they were combined using Boolean operators as needed as shown in **Table 2.2**.

Using these search terms and other searching mechanisms, 4,632 journal articles were found. Using study title, 287 journal articles were selected based on their relevance to the respective themes or subject headings. Furthermore, abstracts were reviewed to select 212 articles relevant to the specific themes as indicated in **Table 2.2**. Studies involving non-food interventions were excluded. In addition, more than 70 reports, working papers, theses and other grey literature were retrieved from Google search and Flinders University library special collection of which more than 20 were related to HIV, nutrition and nutritional programs and were included in this literature review.

Table 2.1: Subject heading and search terms

Broader concept		Searching terms
Links between undernutrition and HIV	Causes of undernutrition	(Malnutrition OR Undernutrition) AND (HIV OR AIDS OR "acquired immunodeficiency syndrome")
	Magnitude of undernutrition	("Human Immunodeficiency Virus" OR HIV OR AIDS) AND (Undernutrition OR Malnutrition) AND "sub-Saharan Africa"
Impacts of undernutrition on mortality, survival, ART adherence and	Undernutrition, mortality and survival	(Malnutrition OR Undernutrition) AND mortality AND (HIV OR AIDS) AND "sub-Saharan Africa"
quality of life	Undernutrition and ART adherence	(Malnutrition or Undernutrition) AND "ART Adherence "AND (HIV or AIDS) AND "sub-Saharan Africa"
	Undernutrition and quality of life	(Malnutrition or undernutrition) AND "quality of life" AND (HIV OR AIDS)
Nutritional program in HIV in sub-Saharan	Forms of nutritional support	("Food by prescription" OR " Ready to Use Food Therapy" OR "Plumpynut" OR
Africa	Nutritional support in selected sub- Saharan African countries	"supplementary feeding" OR "generic food ratios") AND (HIV OR AIDS) AND "sub-Saharan Africa"
Does nutritional support improve nutritional status, survival and ART adherence	Role of nutritional support in improving nutritional status	"Nutritional support" AND (HIV OR AIDS) AND ("Nutritional recovery" OR "Improved BMI" OR "Improved nutritional status") AND "sub-Sharan Africa"
	Nutritional support and survival	"Nutritional support" AND (Survival OR Mortality) AND (HIV OR AIDS) AND "sub-Saharan"
	Nutritional support and ART adherence	"Nutritional support" AND (HIV OR AIDS) AND "ART adherence" AND sub- Saharan Africa
Challenges of nutritional program	Nutritional outcomes	("Nutritional outcomes" OR "Food by Prescription") AND (HIV OR AIDs) AND "sub-Saharan Africa"
	Factors that affect program utilisation	("Nutritional program utilization "OR "Nutritional program adherence" OR" Food by Prescription adherence") AND (HIV OR AIDS) AND "sub-Saharan Africa")

Table 2.2: Search results and final screened evidence for the literature review

Broader concepts	Sub concepts	Total output	Duplicates	Screened by title and abstract	Finally included in the e review
Links between HIV and undernutrition	Causes of undernutrition Magnitude of undernutrition in sub-Saharan Africa	699	233	58	37
Impacts of undernutrition on HIV mortality, survival, ART	Undernutrition, mortality and survival	1245	162	58	25
adherence and quality of life	Undernutrition and ART adherence	163	17	20	12
	Undernutrition and quality of life	234	51	17	9
Nutritional program in HIV care in sub-	Forms of nutritional support	112	33	24	10
Saharan Africa	Nutritional support in selected sub- Saharan African countries	Grey lite governn	15		
Impact of nutritional support on improving nutritional status, HIV mortality and survival and ART adherence	Role of nutritional support in improving nutritional status	828	112	53	40
	Nutritional support and HIV survival	233	34	21	15
	Nutritional support and ART adherence	180	31	15	8
Challenges of nutritional	Nutritional outcomes	324	60	21	16
programs	Factors that affect program utilisation	726	90	29	20
Total outputs		4744		316	221*
Grey literature	Reports, Government documents, thesis,	70	n/a		15+5
Grand total					212

A thematic analysis of the literature was conducted. Thematic analysis is an approach to identify, describe and establish interrelationships within the data (Braun and Clarke 2006) where data refers to the literature in this case. Themes were constructed and developed after an initial exploratory reading of the evidence. Furthermore, the objectives of the study also guided the development of the themes and sub themes used in the literature review. The method involved systematic synthesis of the studies, finding connections and merging similar concepts and ideas together and then refined themes were constructed. Finally, after a critical reading of the literatures, the themes highlighted in the literature review were developed to inform HIV and AIDS and nutrition and identify evidence gaps regarding nutritional programs in HIV care.

2.2 Biomedical context of HIV and AIDS

HIV and AIDS were first documented in mid-1981 as a new health threat but the mechanisms of transmission were not well identified at that time (Gallo and Montagnier 2003; Mann 1998). There are two strains of HIV named as human immune deficiency-1 (HIV-1) and human immunodeficiency-2 (HIV-2), where HIV-1 is the major public health threat worldwide (Piot et al. 1988). While HIV-1 and HIV-2 are very different in their genetic sequence, both can cause Acquired Immunodeficiency Syndrome (AIDS) (Jaffar et al. 2004; Klatt 2016). HIV infection predisposes the human body to multitude of infections by weakening the immune system (Fauci 2003; Simon, Ho and Abdool Karim 2006; Weiss 2000). HIV leads to destruction of the immune system and development of AIDS, which is characterized by the development of an AIDS defining illness (Klatt 2016; Palmisano and Vella 2011).

The HIV virus was discovered in 1983 (<u>Montagnier 2002</u>). Studies have found average years of progression from HIV infection to the development of AIDS range from 4.4 <u>Morgan and Whitworth (2001)</u> through to 9.4 years (<u>Morgan et al. (2002)</u>. This progression is determined by a range of host related factors such as age, gender, ethnicity and other illness (<u>Touloumi and Hatzakis 2000</u>).

The modes of HIV transmission vary amongst continents, countries and geographic areas. The main mode of HIV transmission in sub-Sharan African is heterosexual while men having sex with men (MSM) and injectable drug users are the most common mode of HIV transmission in Europe and America (Morison 2001). In Latin American, the Caribbean (Piot et al. 2001) and Asia (Ruxrungtham, Brown and Phanuphak 2004) there are a mixture of modes. Mother-to child transmission is also an important mode of HIV transmission, particularly in sub-Saharan Africa (Piot et al. 2001). Irrespective of the level of the endemicity of HIV, key populations such as men who have sex-with men, injectable drug users, incarcerated people, commercial sex workers and their clients and transgender people play a vital role in the transmission of HIV (Fettig et al. 2014).

2.3 Links between HIV and AIDS and undernutrition

HIV and undernutrition act on the immune system synergistically and in a vicious cycle contributing to severe immune suppression, which leads to rapid disease progression, morbidity and early mortality (<u>Anabwani and Navariob 2005</u>). Undernutrition affects the immune system by reducing the numbers of key immune system's cells (CD4 and CD8 T-lymphocyte), thus reducing the body's ability to identify and kill infectious agents (<u>Suttajit 2007</u>). In turn, HIV causes immune impairment leading to undernutrition and further immune system damage (<u>Duggal, Chugh and Duggal 2012</u>; <u>Obi 2015</u>).

Advanced HIV disease leads to increased nutrient requirements and undernutrition may result if these are not adequately addressed (<u>Piwoz and Preble 2000</u>). In turn, undernutrition facilitates the rapid progression of HIV infection to AIDS (<u>Malvy et al. 2001</u>; <u>Nshait' and SanGiovanni 1997</u>; <u>Schaible and Stefan 2007</u>). Infections are more frequent, long lasting and severe in undernourished people living with HIV. Thus, both undernutrition and HIV result in an altered host defence mechanism and reinforce the rapid progression of HIV infection to AIDS and the worst clinical outcomes (Anabwani and Navariob 2005).

Undernutrition is a major contributor to child deaths in developing countries, mainly in low resource settings. More than 50% of child deaths in general are attributed to undernutrition (Grover and Ee 2009). When coupled with HIV, mortality and morbidity of children because of undernutrition increase exponentially. Undernutrition and HIV infection in children are also interwoven, with HIV causing undernutrition and undernutrition leading to rapid HIV disease progression (Heikens et al. 2008). Similar to adults living with HIV, undernutrition in children with HIV notably plays a synergistic role in facilitating disease progression, causing growth and developmental retardation (Anabwani and Navariob 2005).

2.3.1 Causes of undernutrition among people living with HIV

Undernutrition is common among people living with HIV mainly because of the clinical effects of the disease but also from the social issues that many people living with HIV face. The clinical effects of HIV infection related to undernutrition include: a) loss of appetite and difficulty in eating, side effects of HIV medications, and disease related depression resulting in reduced food intake; b) poor absorption of nutrients because of recurrent or chronic diarrhoea and HIV-caused intestinal cell damage; c) increased energy requirements as a result of virus replication and opportunistic infections and; d) changes in the way the body stores and uses nutrients, or altered metabolism (Duggal, Chugh and Duggal 2012; Mangili et al. 2006). Social issues such as poverty, food insecurity and other factors also contribute to undernutrition and exacerbate these issues. The relationship between HIV and undernutrition is depicted below (Figure 2.1).

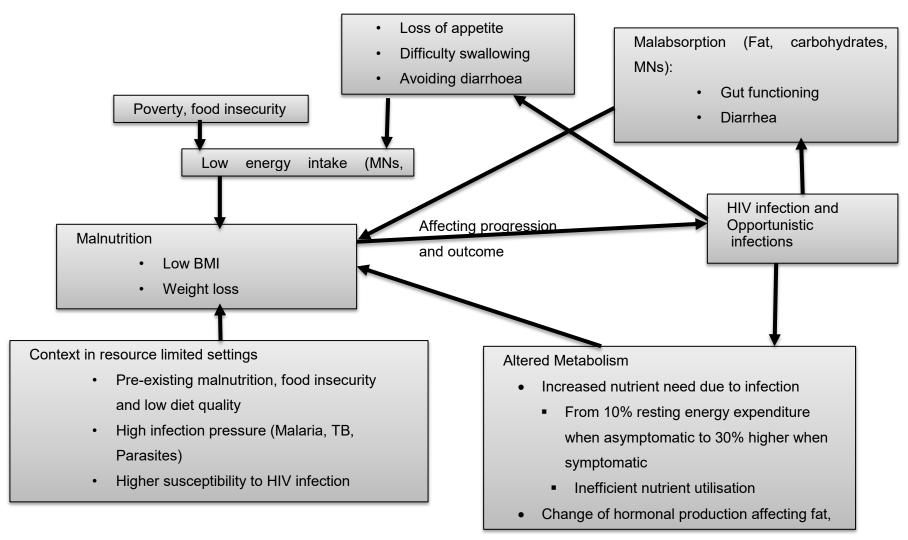


Figure 2.1: Relationship between HIV infection and undernutrition (de Pee and Semba 2010).

Decreased food intake can be related to lack of appetite and difficulty in swallowing (<u>Duggal, Chugh and Duggal 2012</u>; <u>Himmelgreen et al. 2009</u>; <u>Koethe and Heimburger 2010</u>). This mainly results from the oral and gastrointestinal infections common among people living with HIV (<u>Koethe and Heimburger 2010</u>). In addition, loss of appetite can also be attributed to fever, side effects of medicines (antiretroviral drugs) or depression following acquisition of infection (<u>Duggal, Chugh and Duggal 2012</u>).

Malabsorption of nutrients related to intestinal problems such as infection and diarrhoea contribute to undernutrition in people living with HIV (<u>de Pee and Semba 2010</u>). Drug and alcohol abuse as coping mechanisms and intestinal parasites may also contribute to malabsorption followed by undernutrition (<u>Faintuch</u>, <u>Soeters and Osmo 2006</u>).

Another cause of undernutrition among people living with HIV is increased energy expenditure. For those with HIV, resting energy expenditure increases by 10%–30% in adults and 50%–100% in children because of opportunistic infections, which in turn enhances vulnerability to undernutrition (de Pee and Semba 2010; Koethe and Heimburger 2010).

Social factors such as poverty, gender inequality, health service access and utilisation, cultural factors and stigma also contribute to undernutrition through food insecurity (<u>Himmelgreen et al. 2009</u>). Food insecurity is a broad concept and there is lack of clarity on what food insecurity encompasses among people living with HIV. However, one key definition of household food security is "the ability of the household to acquire the food needed by its members" (<u>Pinstrup-Andersen 2009</u>). The household food insecurity access scale (HFIAS) is commonly used to measure food insecurity in sub-Saharan Africa among people living with HIV (<u>Gebremichael et al. 2018a</u>; <u>Kadiyala and Rawat 2013</u>; <u>Sholeye et al. 2017</u>; <u>Tiyou et al. 2012</u>). Food insecurity is measured using a range of questions, while individual diet quality is measured by a dietary diversity score that involves a series of questions about the quality of diet of the individual (<u>Knueppel</u>, <u>Demment and Kaiser 2010</u>; <u>Pinstrup-Andersen 2009</u>; <u>Swindale and Bilinsky 2007</u>).

Food insecurity is a precursor of undernutrition and is widespread among people living with HIV or AIDS in poor resource settings (Obi, Ifebunandu and Onyebuchi 2010; Weiser et al. 2011). Studies from Uganda and Ethiopia reported that 38% and 63% respectively of people living with HIV on ART were food insecure (Tiyou et al. 2012; Tsai et al. 2011). Furthermore, high levels of food insufficiency and low dietary diversity was reported in a study conducted in Rwanda among women living with HIV (Sirotin et al. 2012). The highest levels of food insecurity reported among people living with HIV was 89.5% in Senegal, West Africa (Benzekri et al. 2015).

Reduced intake can also be related to poverty as a result of prolonged illness, loss of productivity or inability to work (Colecraft 2008). For people living with HIV, inability to work can also be related to stigma associated with HIV contributing to low-income, leading to inadequate access to food followed by undernutrition (Audain et al. 2015; Colecraft 2008). Culture also plays a vital role in HIV testing, care and support (Airhihenbuwa and Webster 2004) and contributes to food insecurity and undernutrition by limiting individuals' dietary patterns and food choices (Colecraft 2008).

Inequalities such as gender and income inequality also contribute to undernutrition either directly or through food insecurity (<u>Gillespie 2008</u>; <u>Himmelgreen and Romero-Daza 2008</u>) and greater income inequality is associated with higher levels of HIV or AIDS (<u>Gillespie 2008</u>). In addition, women are more vulnerable to the direct and indirect impacts of HIV, such as poverty and food insecurity (<u>Gillespie 2008</u>; <u>Masanjala 2007</u>).

Furthermore, access to and utilisation of health services is influenced by food insecurity and undernutrition among people living with HIV. For instance, food insecurity creates a competing need between fulfilling food needs and seeking care (Weiser et al. 2012). Moreover, lack of access to health services is a common problem that can result in the late diagnosis of HIV or other opportunistic infections, thereby worsening nutritional deficiency (Kiwanuka et al. 2008).

2.3.2 Undernutrition in people living with HIV in sub-Saharan Africa

Undernutrition and HIV are syndemic³ conditions that affect millions of people in sub-Saharan Africa. According to Musumari et al. (2015) based on a number of reports (FAO and WFP 2012; Joint United Nations Programme on HIV/AIDS 2012), nearly 70% of people living with HIV and 25% of undernourished people globally live in sub-Saharan Africa. Interaction between the clinical and social factors amplify weight loss and poor nutritional status in people living with HIV, which in turn affect health outcomes (Colecraft 2008). Thus, nutritional problems have remained a critical challenge among people living with HIV in poor resource settings such as sub-Saharan Africa (Koethe and Heimburger 2010; Koethe et al. 2009).

There is limited comprehensive evidence (involving multiple countries) on the magnitude of undernutrition in sub-Saharan Africa, and studies about children living with HIV are scarce. Rates of undernutrition in adults varies widely, from 19.4% to 46.8% (**Table 2.3**). A meta-analysis conducted in selected countries in sub-Saharan African found that 10.3% of women aged 15-49 years living with HIV were undernourished, but no figures were given for males (<u>Uthman 2008</u>).

Figures for undernutrition in Ethiopia vary from 23% to 46.8% depending on the season and the susceptibility of the study location to food insecurity and undernutrition (Berhe, Tegabu and Alemayehu 2013; Hadgu et al. 2013; Mitiku et al. 2016; Mulu, Hamza and Alemseged 2016). For instance, a study conducted in southwestern Ethiopia reported that 46.8% of adults living with HIV were undernourished (Mulu, Hamza and Alemseged 2016). In another study in northern Ethiopia, 42.3% of women on ART were found to be suffering from undernutrition (BMI<18.5%) (Hadgu et al. 2013), which was one of the highest rates among studies. Hadgu et al. (2013) found that in northern Ethiopia, almost 40% of study participants living with HIV were diagnosed with undernutrition and enrolled in a nutritional program. However, those with undernutrition may have been recruited systematically in the studies which reported high levels of undernutrition in Ethiopia. For instance Mulu, Hamza and Alemseged (2016) recruited hospitalized people living with HIV, who usually have the poorest nutritional status because of infections. On the other hand, Mitiku et al. (2016) reported that 23.2% of adults living with HIV were undernourished (BMI<18.5kg/m²). This study was conducted in an outpatient setting and may be a better estimate of undernutrition among people living with HIV (Table 2.3).

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³ Syndemic is a set of linked health problems involving two or more afflictions, interacting synergistically, and contributing to excess burden of disease in a population.

In the small number of studies of undernutrition in children living with HIV, rates were worse than for adults. Studies have demonstrated higher rates of undernutrition in children living with HIV compared with those who are HIV negative. For example, a study conducted in Uganda found the extent of underweight among HIV positive children was 53%, compared with 30% in HIV negative children (Nalwoga et al. 2010). Similarly, a study in South Africa reported poorer nutritional status among HIV positive children than their HIV negative counterparts (Kimani-Murage et al. 2011). A study from Zambia also found high levels of developmental problems such as stunting among children living with HIV (Pedrini et al. 2015), while in western and central Africa Jesson et al. (2015) found that 42% of HIV infected children were undernourished. A study from Tanzania also reported severe undernutrition in children living with HIV (Sunguya et al. 2011). In Ethiopia there has been only one study of undernutrition in children living with HIV which this found 20.3% of children with moderate and 15.1% with severe underweight, 12% with moderate and 19.7% with severe stunting, 12.6% with moderate and 13.9% with severe wasting (Alebel et al. 2018) (Table 2.3).

Table 2.3: Summary of prevalence of undernutrition among people living with HIV in sub-Saharan Africa

Authors	Sample size	Population	Location	Undernutrition (BMI<18.5kg/m²)			
Adults							
<u>Uthman (2008)</u>	11 countries	Women aged 15-49	sub-Saharan	10.3%			
	(n=112,657)	years	Africa				
Nnyepi (2009)	145	Adults	Botswana	28.5%			
Hadgu et al. (2013)	273	Women only	Ethiopia	42.3			
Berhe, Tegabu and Alemayehu (2013)	174	Adults	Ethiopia	42.5%			
Benzekri et al. (2015)	109	Adults	Senegal	26.3%			
Sicotte et al. (2015)	250	Adults	Mali	36%			
Mulu, Hamza and Alemseged (2016)	109	Adults	Ethiopia	46.8%			
Mitiku et al. (2016)	453	Adults	Ethiopia	23.2%			
Sidibé et al. (2017)	184	Adults	Guinea	19.6%			
Kabalimu, Sungwa and Lwabukuna (2018)	140	Adults	Tanzania	19.4%			
		Children					
Nalwoga et al. (2010)	5951	Children (0−12 years)	Uganda	42% stunted, 30% underweight and 10% wasted			
Kimani-Murage et al. (2011)	671	12-59 months	South Africa	18% stunted 10% underweight and 7% wasting			
Sunguya et al. (2011)	213 HIV positive and 202 HIV negative	6-60 months	Tanzania	36.6% stunted, 22.1% underweight, 13.6% wasted			
Pedrini et al. (2015)	140	Under 15 years	Mozambique	68% stunted			
Jesson et al. (2015)	1350	2-19 years	West and central Africa	42% undernourished			

Alebel et al. (2018)	390	<15 years	Ethiopia	Stunted 19.7%, wasted,13.9, and
				underweight 15.1%

2.4 Impact of undernutrition on mortality, ART adherence, and quality of life

Given the strong interactions between undernutrition and HIV and AIDS, the impacts of undernutrition on the clinical and immunological outcomes of people living with HIV are potentially devastating. Undernutrition in people living with HIV causes higher rates of morbidity and mortality and decreases survival and longevity because of HIV disease. Despite tremendous achievements in reversing the epidemic of HIV and AIDS and improved treatment, care and support, undernutrition remains a fundamental threat to the successes gained.

2.4.1 Undernutrition and mortality

Undernutrition and its poor management is the most common cause of mortality and morbidity among people living with HIV and AIDS in resource poor settings, while undernutrition at HIV diagnosis and ART initiation is strongly linked to early mortality. According to quantitative studies conducted in sub-Saharan African countries such as Gambia (Van der Sande et al. 2004), Zambia (Stringer et al. 2006) and Zambia and Tanzania (Woodd et al. 2016), poor nutritional status at HIV diagnosis was a strong and independent predictor of mortality. For instance, Van der Sande et al. (2004) found that baseline BMI at HIV diagnosis strongly predicted early mortality with an increasing gradient of mortality with the severity of undernutrition. They found that a BMI<18kg/m² increased the risk of mortality by threefold and BMI<16kg/m² by more than sixfold (Van der Sande et al. 2004). In Zambia, individuals with BMI<16kg/m² were two times more likely to die than those with BMI>18.5kg/m² (Stringer et al. 2006). Research from sub-Saharan Africa also suggests that the contribution of undernutrition to mortality was more pronounced during the early period of ART initiation (Kihulya, Germana and Elia 2012; Liu et al. 2011; Zachariah et al. 2006; Zachariah et al. 2009b).

In Ethiopia, the link between poor nutritional state and mortality was also found (<u>Tadesse, Haile and Hiruy 2014</u>; <u>Tesfamariam, Baraki and Kedir 2016</u>). For example, <u>Tesfamariam, Baraki and Kedir (2016)</u>, found that individuals with undernutrition (BMI <18.5 kg/m²) were five times more likely to die than those with BMI >18.5kg/m². In addition, <u>Tadesse, Haile and Hiruy (2014)</u> found that low weight (<40kg) was associated with mortality among people living with HIV on ART.

However, another study conducted in Ethiopia found no significant relationship between undernutrition and mortality (<u>Hussen, Belachew and Hussien 2016</u>). This may be due to a relatively small sample size (n=340 and 42 mortality) and the sampling (<u>Hussen, Belachew and Hussien 2016</u>) process, in which an equal number of undernourished and well-nourished participants were selected in an attempt to determine differences in mortality.

Similar to adults, undernutrition as defined by low BMI, weight-for-height (W/H) or weight-for-age (W/A) was a strong predictor of early mortality in children living with HIV (Fergusson et al. 2009; Geng et al. 2013). For instance, according to a study conducted in Uganda by Geng et al. (2013), undernourished HIV positive children on pre-ART were three times more likely to die than those who were better nourished.

The link between undernutrition and mortality was similar in children who were on pre-ART and ART, with slightly higher rates of mortality among children on pre-ART. Evidence from Malawi (Bong et al. 2007), Democratic Republic of Congo (Callens et al. 2009), Zambia (Bolton-Moore et al. 2007; Ebissa, Deyessa and Biadgilign 2015) and a study conducted in three sub-Saharan African countries (Marazzi et al. 2014) has shown that undernutrition in children living with HIV predicted mortality in the early period of ART initiation. For example, in the study in Malawi, weight for height <70% or severe wasting was an independent predictor of mortality in the first three months of ART initiation among children living with HIV (Bong et al. 2007).

In Ethiopia, <u>Ebissa</u>, <u>Deyessa and Biadgilign (2015)</u> found that children living with HIV with moderate or severe wasting were 6 and 10 times respectively more likely to die compared with well-nourished children. In contrast, another Ethiopian study found that no anthropometric characteristics were related to mortality in HIV positive children (<u>Edessa</u>, <u>Asefa and sheikahmed 2015</u>). However, this may be because undernutrition was allocated into different categories such as underweight, stunting and wasting during analysis, which may have contributed to the absence of relationships between undernutrition and mortality in children.

2.4.2 Undernutrition and ART non-adherence

There is limited evidence about the impact of undernutrition on ART adherence in other parts of sub-Sharan Africa. A book chapter by <u>Musumari et al. (2015)</u> and another study by <u>Sicotte et al. (2015)</u> both implied the importance of undernutrition in ART adherence mainly in adults, but there was no evidence regarding children.

However, in studies conducted in Ethiopia, undernutrition has remained a critical challenge for ART adherence, particularly in adults (<u>Berhe, Tegabu and Alemayehu 2013</u>; <u>Bitew et al. 2014</u>; <u>Negash et al. 2016</u>). For instance, a case controlled study in Ethiopia found that individuals with BMI<18.5kg/m² were 10 times more likely to be non-adherent to ART than those with BMI>18.5kg/m² (<u>Berhe, Tegabu and Alemayehu 2013</u>). These results were consistent with another study conducted in Ethiopia where adults living with HIV who were undernourished were less likely to adhere to ART (Negash et al. 2016).

Musumari et al. (2015) and Sicotte et al. (2015) argued that undernutrition may constrain or enhance ART adherence. While decreased muscle mass and lack of energy can reduce patients' ability to attend ART clinics, poor nutrition can lead to closer attention and follow-up in HIV care, leading to better adherence. However, some evidence included in the book chapter by Musumari et al. (2015) was not published (Master's thesis). The unpublished study conducted in Ethiopia did not find a relationship between undernutrition and ART adherence (Seifu 2007) yet Musumari et al. (2015) claimed that undernutrition leads to ART adherence based on the unpublished Ethiopian study in his book chapter.

Research has indeed found a linked between food insecurity and poor ART adherence in adults (Berhe, Tegabu and Alemayehu 2013; Goudge and Ngoma 2011; Musumari et al. 2014; Singer, Weiser and McCoy 2015). Suggested pathways included a) beliefs that ART required food to be effective, so that people living with HIV did not take ART medication when food was not available, b) fear of ART side effects if medications could not be taken with food and c) "competing needs between food and ART" where the individual has to choose between going to collect ART or obtaining food (Musumari et al. 2015).

There was little evidence on the relationship between undernutrition and ART adherence in children. However, according to a qualitative study conducted in sub-Saharan Africa, undernutrition was a factor contributing to ART non-adherence in children living with HIV (Fetzer et al. 2011) but there was no insight as to the mechanisms through which undernutrition can contribute to ART non-adherence in children living with HIV. There was only one study regarding food insecurity and ART adherence in children which reported the contribution of food insecurity to ART non-adherence in children (Young et al. 2014).

2.4.3 Undernutrition and quality of life among HIV patients

According to the WHO, Quality Of Life (QOL) is "an individual's perception of their position in life in the context of their culture and value systems in which they live and in relation to their goals, standards, expectations and concerns" (WHO 1998, p 2). Health Related Quality of Life (HQOL) focuses on issues relevant to self-evaluated health of an individual (Fang et al. 2002). The WHO uses six domains to measure HQOL among people living with HIV. These domains include a) physical health which includes medical problems such as pain, capacity to work and related issues; b) psychological health such as negative and positive emotions, self-image and cognitive functions c) level of independence which includes mobility, activities of daily living and work capacity, d) social relationships which includes personal relationships, social support and sexuality, e) environmental issues such as economic issues, safety and security of the physical surroundings, f) spirituality, religion and personal belief (WHO 2002).

Undernutrition potentially affects quality of life among people living with HIV through facilitation of disease progression (Suttajit 2007). There is limited evidence examining the association between HIV and quality of life, but studies conducted in low resource settings in south Asia, such as India (Bhowmik et al. 2012) and Nepal (Thapa et al. 2015) have indicated a correlation between undernutrition and quality of life domains. For example, Thapa et al. (2015) found weight, height and BMI were positively correlated with the domains of quality of life.

There is little research in sub-Saharan Africa examining the relationship between undernutrition and poor HQOL. One study conducted in Ethiopia found that undernutrition was associated with poor HQOL, and females were most affected (<u>Gebremichael et al. 2018b</u>). However, there was no evidence regarding the relationship between undernutrition and quality of life in children living with HIV.

The importance of food security in improving HQOL is highlighted in many studies (<u>Maluccio et al. 2015</u>; <u>Palermo et al. 2013</u>). In a study conducted in Uganda, food security improved HQOL among adults living with HIV (<u>Palermo et al. 2013</u>). In addition, another study from Uganda also reported that HQOL has improved with food assistance among adults living with HIV (<u>Maluccio et al. 2015</u>).

To sum up, the review of literature confirmed the contribution of undernutrition to early mortality from HIV, ART non-adherence in adults and poor HQOL in adults. Some literatures also support the impact of undernutrition on ART non-adherence. This demonstrates the importance of addressing undernutrition in a holistic approach in HIV care settings. The next section will detail nutritional programs that are implemented in sub-Saharan Africa and types of nutritional supports used in the nutritional programs using purposively selected case countries.

2.5 Nutritional programs in HIV care in sub-Saharan Africa

As presented in the previous sections, undernutrition contributes significantly to poor HIV outcomes. Built on this understanding, the next section summarises the existing knowledge about nutritional interventions in sub-Saharan Africa.

Given that people living with HIV are at risk of undernutrition (Nnyepi 2009), scaling up of HIV services without incorporating nutritional programs may undermine the success gained in the treatment and care of HIV. As a result, the WHO identified nutrition as a critical intervention for people living with HIV on ART and pre-ART and recommended nutritional supplements for undernourished HIV patients and nutrition interventions for orphans and vulnerable children (WHO 2003b). On these grounds, WHO recommended integration of nutritional care and support as an essential component of HIV care and support services (WHO 2008).

Nutritional assessment, counselling and support (NACS) is the main nutritional program used in HIV care in sub-Saharan Africa (Sackey 2016). NACS services are defined as: "a client-centred programmatic approach for integrating a set of priority nutrition interventions into health care services and strengthening health systems to prevent, detect, and treat undernutrition and maintenance of improved nutritional status to prevent relapse" (USAID et al. 2016).

According to the findings of a study from 10 sub-Saharan African countries, 90% of HIV care sites have some form of nutritional care (<u>Anema et al. 2012</u>). However, there was a substantial variation in nutritional programs in HIV care by country, geographic context (urban vs rural) and site level characteristics such as type of site (primary, secondary or tertiary levels of care), age of the program, and the presence of a nutritionist in the program. The diversity of nutritional programs in sub-Saharan African countries is shown in **Figure 2.2**.

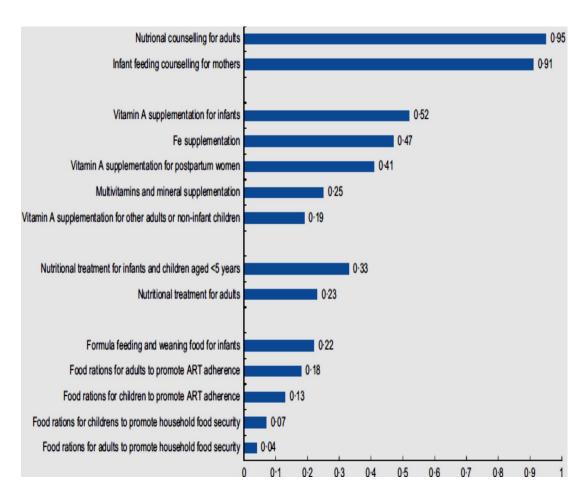


Figure 2.2: Types of nutritional interventions and their proportions in sub-Saharan Africa (Anema et al. 2012).

Nutritional assessment among people living with HIV should involve at least measurement of weight and height to calculate BMI, MUAC and assessment of dietary practices including eating pattern and intake, appetite and eating problems and household food security (<u>WHO 2004</u>). The literature on the extent and appropriateness of nutritional assessment in HIV care is however, limited (Anema et al. 2012; Sackey et al. 2018; Tang et al. 2015).

Nutritional counselling, provision of nutritional support and micronutrient supplementation are other elements of nutritional programs implemented in many sub-Saharan African countries. Nutritional counselling to ensure the proper utilisation, preparation and storage of foods is a crucial component of nutritional programs in HIV care. The aims of nutritional counselling in HIV care is to assist patients a) "maintain weight through increased energy intake", b) practice "safe infant feeding", c) practice "safe food or water handling" and d), "manage HIV related illness" (Food and Nutrition Technical Assistance (FANTA) 2004; WHO 2004).

There was mixed evidence on the availability and practice of nutritional counselling in sub-Saharan Africa (Anema et al. 2012; Sackey et al. 2018). For instance, a study showed the presence of different forms of counselling and nutritional support of different forms in nutritional programs, with nutritional counselling included in about 95% of the study sites, particularly at secondary and tertiary level care sites (Anema et al. 2012). However, this study did not indicate a specific target population for nutritional counselling in terms of their HIV or nutrition status, such as ART or pre-ART and undernourished or normal or overweight. In addition, duration, content and forms of the nutritional counselling were not indicated.

Another study conducted in Ghana examined the implementation of NACS by conducting direct observation and reported a lack of nutritional counselling (<u>Sackey et al. 2018</u>). A systematic review of nutritional assessment, counselling and support also reported lack of proper nutritional counselling in HIV care, indicating an important challenge for nutritional programs in HIV care (<u>Sackey 2016</u>). Hence, the evidence about the content, duration and forms of nutritional counselling in HIV care services in sub-Saharan Africa is inadequate.

2.5.1 Range of nutritional support

The type and composition of nutritional support in HIV care varies by program, geographic location, nutritional status of the beneficiaries, and the availability of funding. Protein—energy undernutrition is the most common type of undernutrition in sub-Saharan Africa (Musumari et al. 2015). To tackle this, HIV treatment and care programs in sub-Saharan Africa mainly provide food-based supplements such as high energy, protein and fat diets (Mamlin et al. 2009).

Food-based supplements are available in different forms: 1) high-energy ready-to-use therapeutic foods (RUTF), 2) corn-soy-blended (CSB), or 3) fortified blended foods, high-energy biscuits and compressed food bars (Grobler et al. 2013). According to Anema et al. (2012), food based nutritional supports were available in 31% of HIV treatment sites commonly comprising CSB, fortified blended foods and RUTF. Therapeutic ready-to-use foods for undernourished people were only available in 36% of HIV care and treatment sites (Anema et al. 2012). In sub-Saharan Africa, RUTF (Plumpynut/Plumpysup), CSB and food rations were commonly used in HIV care programs (Ahoua et al. 2011; Anema et al. 2012; Food and Nutrition Technical Assistance (FANTA) 2004; Sadler et al. 2012).

2.5.2 Nutritional supports in selected sub-Saharan African countries

Research has shown that nutritional support is the key element of nutritional programs designed to improve nutritional status, decrease mortality, improve survival, and enhance adherence to ART. The case countries reported herein were selected based on their location in sub-Saharan Africa and the availability of program information from online sources. Nutritional programs in HIV care use different types of nutritional support. Even though they are slightly different in their form, content, and packaging, RUTF and CSB were the most common forms of nutritional supports. Details of nutritional programs in the selected case countries in sub-Saharan Africa are summarized below and in **Table 2.4**

Table 2.4: Similarities and differences in nutritional programs in the case countries in sub-Saharan Africa

References	Name of country	Content	Enrolment criteria	Target population
Castleman and Diene (2015); Scarcella et al. (2011).	Mozambique	-RUTF -CSB -Other food rations	BMI<18.5kg/m ² for undernourished but no clear criteria for well- nourished	Well-nourished Undernourished
Cantrell et al. (2008); National Food and Nutrition Commission (NFNC) of Zambia (2011)	Zambia	-RUTF -CSB	BMI<18.5kg/m ²	Undernourished
USAID and Nulife (2010) Rawat, Kadiyala and McNamara (2010).	Uganda	-RUTF -CSB	BMI<18.5kg/m2	Undernourished
Dibari et al. (2012); Food and Nutrition Technical Assistance II Project (FANTA- 2) (2009); Nagata et al. (2014); Ndirangu et al. (2014); USAID and AIDSTART One (2010).	Kenya	-RUTF -CSB -Other food rations	BMI<18.5kg/m2 for undernourished and evidence of food insecurity for those with no clinical undernutrition	Undernourished Food insecure
Anthony and Jayashankar (2009); Sadler et al. (2012)	Ethiopia	-RUTF	BMI<18.5kg/m2	Undernourished

The nutritional program in Ethiopia started in 2010 and the nutritional support used in the nutritional program are RUTF supports, a Plumpynut® paste for severe acute undernutrition, and RUSF, Plumpy'Sup® paste for moderate acute undernutrition (<u>Anthony and Jayashankar 2009</u>; <u>Sadler et al. 2012</u>). A detailed description of the nutritional program in Ethiopia is given in the Introduction chapter of this thesis (**section 1.4**).

There is no specific model for nutritional programs for children living with HIV in the countries described above. Community based management by using of RUTF/RUSF has been used for children aged under five years suffering from undernutrition (regardless of their HIV status) and has been shown to be effective in overcoming undernutrition amongst children (Sadler et al. 2006) (Ciliberto et al. 2005; Collins et al. 2006; Karakochuk et al. 2012).

2.6 The impact of nutritional support on improving nutritional status, HIV survival and ART adherence

This section summarises the evidence on the impact of nutritional support on improving nutritional status, HIV survival and ART adherence.

2.6.1 Role of nutritional support in improving nutritional status

Adults

There is growing evidence that shows the use of nutritional support for undernourished people living with HIV is associated with improved nutritional status (<u>de Pee and Semba 2010</u>; <u>Koethe et al. 2009</u>; <u>Tirivayi and Groot 2011</u>). However, this impact varies depending on the type, duration of nutritional support and baseline nutritional status of people living with HIV.

A review by Tirivayi and Groot in low resource settings found that nutritional support involving RUTF or RUSF was associated with improved BMI among undernourished people on ART (<u>Tirivayi and Groot 2011</u>). However, the authors suggested that the results should be interpreted cautiously because of methodological issues and differences in implementation of the nutritional support programs, for example the inclusion of other income generating activities. Another review conducted in resource adequate and resource constrained settings clearly indicated that nutritional support using RUTF was associated with improved BMI (<u>Koethe et al. 2009</u>). However, while the review noted adequate evidence in resource adequate settings, the quality of evidence in resource poor setting was weaker largely because of the small number of studies.

Generally, the evidence provided in the reviews were inadequate about the role of nutritional support in improving nutritional status in sub-Saharan Africa. In addition, many studies from sub-Saharan Africa were not included because the aim of the reviews was not exactly the impact of nutritional support on nutritional status, and some of the studies in sub-Saharan Africa were conducted after the above reviews.

Studies undertaken in sub-Saharan Africa have provided stronger evidence on the association of nutritional support involving RUTF with an improved nutritional status among adults living with HIV (Bahwere et al. 2011; Bahwere, Sadler and Collins 2009; Diouf et al. 2016; Mallewa et al. 2018; Ndekha et al. 2009b). For instance, a study conducted in Malawi on the acceptability and effectiveness of RUTF (median of 300g/day/person) for undernourished adults reported that 73.3% of participants gained weight, MUAC and BMI (Bahwere, Sadler and Collins 2009). The researchers also demonstrated that wasted individuals gained an average 19.1g in weight for each 1000 kilocalorie (kcal) of nutritional support.

In another study conducted in Malawi comparing RUTF and CSB among undernourished adults living with HIV, weight gain and improvement in BMI were seen with both types of nutritional support (Ndekha et al. 2009b). This study design was strong because it used comparison groups and had a prospective randomized, controlled and investigator blinded follow-up study. In the same vein, a similar study from Malawi reported that nutritional support using RUTF was associated with improved nutritional status of wasted adults living with HIV, but results of this study should be interpreted with caution because there was no control group and the sample size was small (n=154) (Bahwere et al. 2011).

In more recent studies from Senegal (Diouf et al. 2016) and other countries in sub-Saharan Africa (Mallewa et al. 2018), nutritional support improved the BMI of undernourished people living with HIV. Olsen et al. (2014) demonstrated changes in BMI after provision of nutritional support in Ethiopia, but the difference between those who received the nutritional support and those who did not was not statistically significant. While the study conducted in Senegal had a strong design, care should be taken when interpreting the findings of other studies conducted in sub-Saharan Africa and Ethiopia because of their observational nature and lack of comparison groups.

Despite the differences in duration of nutritional support, nutritional status of people living with HIV at enrolment and status of household food insecurity, nutritional supports involving RUTF resulted in improved nutritional status in all studies reviewed (**Table 2.5**).

Table 2.5: Summary of literature on the role of nutritional support and its impact in improving nutritional status in sub-Saharan Africa

Authors	Sample size and study design	Population	Location	Type of nutritional support and duration	Improved nutritional status
Bahwere, Sadler and Collins (2009)	63, follow up study	Wasted adult people living with HIV	Malawi	Chickpea sesame- based RUTF for 3	Change in weight=3.4kg
<u>and Comms (2003)</u>	Study	iiviiig widi i ii v		months	Change in MUAC =25.4mm
					Change in BMI=1.1kg/m²
Ndekha et al. (2009b)	491, controlled blind	Undernourished people living with HIV	Malawi	RUTF and CSB for 3.5 months	BMI gain in RUTF=2.2kg/m ²
<u>(2009b)</u>	interventional study	people living with this		Months	BMI gain in CSB=1.7kg/m ²
Bahwere et al. (2011)	194, interventional study	Wasted and confirmed or suspected AIDS patients	Malawi	Chickpea sesame based RUF 3 to 5 months	Mean weight gain 2.3kg and significant improvement from enrolment weight
Olsen et al. (2014)	318 randomized controlled trial	People living with HIV with BMI>16kg/m ²	Ethiopia	Lipid based nutritional supplement (whey or soy) for three months	Mean BMI increase =0.85 kg/m ²
Diouf et al. (2016)	65, randomized controlled trial	Undernourished people living with HIV	Senegal	Peanut based RUF for 9 months	11% increase in body
Mallewa et al. (2018)	1805, interventional randomized study	Severely undernourished adults and children living with HIV	Kenya, Malawi, Uganda, and Zimbabwe	Peanut-based RUSF and RUF for 3 months	Both resulted in improved weight and BMI

In terms of other forms of nutritional support, there is contrasting evidence on the impact of non-ready to use and less energy dense foods or generic food rations in improving BMI and the nutritional status of people living with HIV. The systematic review conducted by Irrivayi and Groot (2011) examined five primary studies which looked at the impact of food assistance on weight gain among well-nourished people living with HIV to prevent weight loss. The review found that nutritional support involving RUTF and CSB provided to well-nourished people living with HIV on ART was associated with weight gain. However, weight gain was not maintained 12 weeks after cessation of the nutritional support. In a study conducted in Malawi using CSB, an association was found between the use of nutritional support and weight gain among wasted adult people living with HIV (Ndekha et al. 2009b). This study had a relatively strong design but did not provide information regarding the level of utilisation of the nutritional support. A similar finding was seen with generic food rations in Uganda (Rawat, Kadiyala and McNamara 2010). However, this study was unable to verify and assess whether participants consumed the nutritional support themselves and there was also no comparison group.

Food packages involving cereals, peanuts, pulses, sugar and corn soy blend improved BMI in undernourished people living with HIV in Mozambique (Scarcella et al. 2011). A study from South Africa that examined the effect of nutritional support involving an instant, enriched maize meal also observed a significant increase in BMI in 42% of participants (Lategan, Steenkamp and Joubert 2010). A similar study in South Africa that compared ART plus nutritional supplement (FutureLife porridge®) and ART only among two groups of HIV positive people found a significant improvement in BMI among those who received ART plus the nutritional support (Evans et al. 2013). However, the studies in Mozambique (Scarcella et al. 2011) (n=106) and South Africa (Lategan, Steenkamp and Joubert 2010) (n=98) both had very small sample sizes which may limit replication of findings.

Other studies found no improvement in weight with generic food rations. A study conducted in Malawi which assessed the role of generic food rations distributed by the World Food Program (WFP) found non-significant weight gain (Bowie et al. 2005). Another study from Zambia involving food insecure people living with HIV also found no effect of generic food rations provided by WFP on weight gain but the duration of provision of the nutritional support was short (six months) and done without assessment of the household food insecurity status (Cantrell et al. 2008) (also refer to the summary of evidence in **Table 2.6**).

In conclusion, the review of the literature highlighted that, in general, nutritional support involving generic food rations targeting undernourished (BMI<18.5 kg)/m²) adults living with HIV was associated with weight gain and improved nutritional status when participants were compared with well-undernourished people living with HIV on ART, although there were some exceptions. However, given the studies' limitations, care should be taken in interpreting the results.

Table 2.6: List of studies showing the relationship between nutritional support involving generic food rations and improvement of nutritional status

Authors	Sample size and study design	Population	Location	Type of nutritional support and duration	Improved nutritional status
Bowie et al. (2005)	360, retrospective cohort	Chronically sick patients receiving home-based care	Malawi	Maize, beans, cereal-soya blend	No statistically significant improvement in BMI
Cantrell et al. (2008)	636, interventional study	Food insecure people living with HIV	Zambia	Fortified corn-soya blend and vegetable oil	No weight gain
Lategan, Steenkamp and Joubert (2010)	98, prospective cohort	To all patients on ART	South Africa	Instant, enriched maize meal, four months	Median BMI increase 1.13 kg among under nourished
Rawat, Kadiyala and McNamara (2010)	14,481, retrospective cohort study	Food insecure people living with HIV	Uganda	Corn soy blended flour, vegetable oil, pulses and maize meal or rice for one to two years	Mean weight gain: 0.36 kg over one-year period.
Scarcella et al. (2011)	106, prospective cohort	People living with HIV with BMI<18.5kg/m ²	Mozambique	Cereals (rice or corn), pulses, peanuts, sugar, sunflower seed oil, fortified corn soy blend for one year	BMI improved from 20.7 ±3.9 21.9 ±3.3 kg/m ²
Evans et al. (2013)	36, randomized interventional study	People living with HIV self-reported weight loss	South Africa	FutureLife porridge® nutritional supplement (NS) (388 kcal/day), for six months	Mean BMI change 7.8 kg/m²

Children

There was limited evidence on the role of nutritional support in improving nutritional status in children living with HIV. RUTF has been used to address undernutrition in both HIV positive and negative children in resource poor settings (Mda 2015). There were only a few studies examining the role of generic food rations in improving nutritional status in children living with HIV. A study from Tanzania reported significant improvement amongst severely wasted and underweight children living with HIV receiving RUTF (Sunguya et al. 2012). A study conducted in South Africa in a clinical setting reported weight gain among children living with HIV who had diarrhoea and who received nutritional support (Rollins et al. 2007). Studies from Malawi and Zambia also found an equivalent improvement in nutritional status among HIV positive and HIV negative undernourished children (Fergusson et al. 2009; Hughes et al. 2009). However, all these studies lacked a comparison group, and thus caution is needed when interpreting the results.

Even though the available evidence is weak, nutritional support involving RUTF has had positive effects on wasting and underweight in children living with HIV, but no research has examined the impact of generic food rations in improving nutritional outcomes in children.

2.6.2 Nutritional support and ART adherence

Optimal adherence to ART is fundamental to improved clinical outcomes such as survival and CD4 count. ART non-adherence is a common challenge in many ART care programs in low-income settings (<u>Bärnighausen et al. 2011</u>; <u>Bitew et al. 2014</u>). Undernutrition and food insecurity are key factors contributing to ART non-adherence as discussed in **sub-section 2.4.2**.

One strategy to improve adherence and patient retention in care is the provision of nutritional support as part of HIV treatment, care and support services. Many studies in low resource settings have found a link between different forms of nutritional support and improved adherence to ART and retention in HIV care (Cantrell et al. 2008; Evans et al. 2013; Tirivayi, Koethe and Groot 2012; van Oosterhout et al. 2010). For instance, Bahwere et al. (2011) indicated that provision of nutritional support involving RUTF and CSB had improved ART adherence. The study by (Tirivayi, Koethe and Groot 2012) found that adults who received food assistance were more likely to adhere than those without assistance (*p*<0.01). Moreover, nutritional support played a pivotal role in improving retention in care and ART adherence in a study from South Africa, where HIV patients who received nutritional support of different composition provided to undernourished people living with HIV improved adherence to ART by providing the energy needed to travel to clinics to collect ART drugs and addressing the perception that ART needs food.

There was no difference in adherence between types of nutritional support and adherence to ART according to two studies conducted in Malawi (Manary, Ndekha and van Oosterhout 2010; Ndekha et al. (2009b). Ndekha et al. (2009b) examined two RUTF foods with ready to use fortified spread or CSB and found no difference in adherence between the two groups. Similarly, Manary, Ndekha and van Oosterhout (2010) found no difference in ART adherence between those who received RUTF and CSB. Hence, there is conclusive evidence on the role of nutritional support in improving adherence to ART despite the type, duration and mode of nutritional support provided in HIV care.

2.6.3 Effect of nutritional support on mortality and survival

There is strong evidence that low BMI is associated with higher HIV mortality (as discussed in **subsection 2.4.1)** but a number of studies that examined the impact of nutritional support involving RUTF on reducing mortality in people living with HIV found no effect (Bahwere et al. 2011; van Oosterhout et al. 2010). For example, nutritional support did not reduce mortality in a study from Malawi which examined the impact of RUTF on adults living with HIV who were suffering from wasting (Bahwere et al. 2011). In another study from Malawi, provision of food support did not decrease mortality after 14 and 26 weeks of supplementation (van Oosterhout et al. 2010). Both these studies were limited by lack of a control group. In addition, van Oosterhout et al. (2010) indicated that adherence to the nutritional support was not measured, which may have undermined its effect on mortality.

Another study from Malawi examining the acceptability and effectiveness of chickpea, sesame-based, ready to use therapeutic food did not find any improvement in mortality, with 18.3% (11/60) mortality over a three-month period (Bahwere, Sadler and Collins 2009). Nevertheless, because of the short duration, small sample size (n=63), lack of control group and absence of baseline mortality, findings of this study were inconclusive. Despite its effect in improving BMI, two other studies from Malawi also found no survival benefits from nutritional support (supplementary feeding) (Manary, Ndekha and van Oosterhout 2010; Ndekha et al. 2009b).

A more recent study involving four countries (Kenya, Malawi, Uganda and Zimbabwe) in sub-Saharan Africa found that nutritional support using RUTF did not have an impact on reducing mortality among people living with HIV (Mallewa et al. 2011). This study was large in terms of sample size (n=1805 participants) and employed an interventional non-randomized trial that enabled a more rigorous design in terms of controlling for confounding.

Overall, despite some limitations in the studies reviewed, there has been a consistent finding that nutritional support involving RUTF did not reduce mortality among adults living with HIV.

A literature gap exists with regards to the role of generic food rations on mortality among adults living with HIV. One study from Malawi which examined the effect of generic food rations on survival of well-nourished but food insecure adults living with HIV found no survival benefits of nutritional support (Bowie et al. 2005). However, in this study, it was difficult to ascertain whether the target persons consumed the food rations themselves.

Immune status is another indicator of survival in AIDS patients and evidence on the role of nutritional support involving RUTF on improved immune status (improved CD4 count) among adults living with HIV was mixed. A randomized controlled trial in South Africa found improved immune status in the group that received ART plus the nutritional supplements compared with the control group, and improvement in physical activity (an indicator of improved immune status) at six months post-ART initiation (Evans et al. 2013). Studies from Malawi (Bahwere, Sadler and Collins 2009) and Ethiopia (Olsen et al. 2014) also found a positive effect of RUTF on immune status and clinical outcomes.

Conversely, a review by <u>Audain et al. (2015)</u>, found no conclusive evidence that nutritional support improved immune status. In general, systematic reviews that compared the impact of various forms of macronutrients supplementation in undernourished adults and children living with HIV found no impact of nutritional supplementation on improved immune status (<u>Grobler et al. 2013</u>; <u>Mahlungulu et al. 2007</u>).

Generally, the extent to which the provision of nutritional support to undernourished persons living with HIV had positive effects in achieving improved nutritional status and adherence to ART may rest on differences in the types of nutritional support, duration and intended target. Provision of nutritional support was not related with reduced mortality while it is mixed regarding the role of nutritional support on improving immune status. Evidence was lacking regarding the role of nutritional support in improving immune status and mortality regarding children living with HIV but provision of RUTF to undernourished adults did not reduce mortality nor improve immune status.

2.7 Effectiveness of nutritional programs in HIV care

Nutritional programs in HIV care settings are intended to address undernutrition and maintain nutritional wellbeing of people living with HIV (Grobler et al. 2013). In sub-Saharan Africa, nutritional programs in HIV care include three key elements, nutritional assessment, counselling and nutritional support (Anema et al. 2012), and aim to restore nutritional status and translate the improvement in nutritional status into improved adherence to ART and improved immune function (Ahoua et al. 2011; Sadler et al. 2012). As indicated in sub-section 2.6.1, nutritional supports involving RUTF and generic food rations have proved effective in improving nutritional status of adults and children living with HIV.

However, despite the role of nutritional supports in improving nutritional status and adherence to ART, the success of programs as measured by nutritional outcomes such as nutritional recovery, program incompleteness, non-response and relapse of undernutrition are unclear (Ahoua et al. 2011; Sadler et al. 2012). The following sub-section discusses the effectiveness of nutritional programs in HIV care in sub-Saharan Africa including determinants of nutritional outcomes and barriers to and facilitators of program utilisation.

2.7.1 Determinants of nutritional recovery

Nutritional recovery is defined as achieving BMI ≥18.5 kg/m² after enrolment in a nutritional program prior or at the end of the duration of the nutritional program. Nutritional recovery among adults enrolled in nutritional programs has been consistently low but varied significantly depending on how recovery was defined, types of nutritional support, criteria for enrolment and duration of the nutrition program (Ahoua et al. 2011; Nagata et al. 2014; Sadler et al. 2012). According to Ahoua et al. (2011) in Uganda and Kenya, and Sadler et al. (2012) in Ethiopia, 47.4% and 11.3% respectively of adults enrolled in a nutritional program using RUTF achieved recovery. The large difference in recovery between these two studies may be explained by the studies' definitions of recovery and their enrolment criteria. Ahoua et al. (2011) defined nutritional recovery as BMI>18.5kg/m² in two consecutive visits and the enrolment criterion was a BMI <17kg/m². Sadler et al. (2012) defined nutritional recovery as achieving a BMI≥18.5kg/m² in two consecutive measurements while the enrolment criterion was BMI<18.5 kg/m² (Sadler et al. 2012). Another study conducted in Ethiopia reported a greater (62%) nutritional recovery among adults living with HIV, which may be attributed to contextual differences (Maldey, Haile and Shumye 2014) (Table 2.7).

In contrast, another study from Kenya which included nutrient-dense, pre-cooked whole maize, soybeans, vegetable oil, and cane sugar fortified with vitamins and minerals found that only 13% of participants achieved nutritional recovery, defined as BMI>20kg/m² while the enrolment criterion was BMI<18.5kg/m² (Nagata et al. 2014).

Nutritional programs that used RUTF (<u>Bahwere, Sadler and Collins 2009</u>; <u>Ndekha et al. 2009a</u>; <u>Sadler et al. 2012</u>) and had longer periods of nutritional support had higher nutritional recovery rates. For instance, a study from Malawi showed that RUTF supplementation led to nutritional recovery (<u>BMI>18.5kg/m²</u>) among people living with HIV and those provided with CSB also achieved reasonable weight gain (2.9 kg (51.8%) of the 5.6 kg) and mean <u>BMI</u> (18.5kg/m²) (<u>Bahwere, Sadler and Collins 2009</u>; <u>Ndekha et al. 2009b</u>). However, the study by <u>Bahwere, Sadler and Collins (2009</u>) lacked comparison groups and had a small sample size (n=63) (**Table 2.7**).

A number of studies have examined the impact of individual characteristics, for example gender and age, on nutritional recovery but the findings were mixed. A study in Kenya in which nutritional recovery was defined as BMI>20 kg/m² found males were more likely to recover than females (Nagata et al. 2014). Higher baseline BMI (less severe undernutrition) and younger age were also associated with nutritional recovery (Nagata et al. 2014). In contrast, being female was associated with nutritional recovery in a study conducted in Ethiopia (Sadler et al. 2012).

Studies have also indicated that those on ART had enhanced nutritional improvement or weight gain in a nutritional program involving RUTF (<u>Bahwere et al. 2011</u>; <u>Diouf et al. 2016</u>). <u>Bahwere et al. (2011)</u> found that adults living with HIV on ART were nearly three times more likely to gain weight than those who did not commence ART. Similarly, a study from Ethiopia found being on ART for less than six months was associated with nutritional recovery (<u>Sadler et al. 2012</u>) (**Table 2.7**).

In contrast, a study conducted in Kenya found that being at the pre-ART stage was associated with nutritional recovery (Nagata et al. 2014). While these studies varied in terms of the role of ART in nutritional recovery, as indicated in **sub-section 2.5.1**, being on ART was associated with improved BMI and facilitated weight gain. The study by Nagata et al. (2014) found differences in baseline nutritional status of participants on ART and pre-ART that may account for some of the contrasting evidence on the role of nutritional support on nutritional recovery.

In a study in Ethiopia, food insecurity and the presence of opportunistic infections such as tuberculosis were related to poorer nutritional recovery among moderately undernourished participants (Sadler et al. 2012). The health care setting (primary health care versus hospital setting) was also a factor influencing nutritional recovery in adults. Sadler et al. (2012) demonstrated that patients attending primary health care services achieved higher rates of recovery compared with those in a hospital setting. The authors speculated that poor clinical conditions and high caseloads in hospitals may explain the difference (Sadler et al. (2012).

There is less research examining nutritional outcomes for children. Recovery from undernutrition in HIV negative children in community based therapeutic care has been reported to be high (76.6%) (Sadler et al. 2006). There is some evidence of differences in nutritional recovery between HIV negative and positive children (Bahwere et al. 2008; Ndekha et al. 2005). Ndekha et al. (2005) found that in a community-based management program for acute undernutrition using RUTF, the recovery rate for HIV-positive children was 56% (achieving 100% weight-for-height) whereas the recovery rate for HIV negative children was 84%. Another study from Malawi reported 59% and 83% recovery in HIV positive and negative children respectively (Bahwere et al. 2008) (Table 2.7).

In terms of predictors of nutritional outcomes for children, in general there were discrepancies in nutritional recovery by HIV status (positive vs negative) and type of nutritional program, such as inpatient therapeutic, outpatient or community-based, as demonstrated above. There was limited evidence demonstrating the effects of children's and caregivers' characteristics and roles in nutritional recovery among children living with HIV. A study from Malawi found that older age, greater weight-for-height *z* scores, absence of oedema, absence of severe thrush (*Candida* spp.), and prompt ART initiation were associated with nutritional recovery (Kim et al. 2012). However, there were only 140 children in the study and the confidence intervals in the odds ratio estimates were very wide. On the other hand, one study conducted in Nigeria found no demographic, clinical or nutritional characteristics were related with nutritional recovery in either HIV positive or HIV negative children (Ige, Oladokun and Kikelomo 2014). Thus, there is no conclusive evidence about the determinants of nutritional recovery in children living with HIV.

 Table 2.7: Nutritional program recovery and its determinants in sub Sharan Africa

Authors	Magnitude nutritional recovery	Country	Determinants		
Adults					
Bahwere, Sadler and Collins (2009) Ndekha et al. (2009b)	Not estimated but reported nutritional recovery Not estimated but reported nutritional recovery	Malawi Malawi	 Use of RUTF as nutritional support Being on ART On ART for less six months 		
Ahoua et al. (2011)	47.4%	Kenya and Uganda	Male genderFood security at baseline		
<u>Bahwere et al. (2011)</u> <u>Sadler et al. (2012)</u>	11.3%	Malawi Ethiopia	Attending the nutritional program at primary health care		
Maldey, Haile and Shumye (2014)	62%	Ethiopia			
Nagata et al. (2014)	13%	Kenya			
Diouf et al. (2016)	Not estimated but reported nutritional recovery	Senegal			
Children					
Ndekha et al. (2005)	56%	Malawi	Older age,		

Bahwere et al. (2008)	59%	Malawi	Greater weight-for-height z scores,
			Absence of oedema,
Kim et al. (2012)	86%	Malawi	 Absence of severe thrush (<i>Candida</i> spp.), Prompt ART initiation
Cames et al. (2016)	21%	Senegal	- Homperatt anddon

2.7.2 Program incompleteness

Research on program incompleteness, withdrawal from a nutritional program before the predefined exit criteria, has found major discrepancies across studies (Ahoua et al. 2011; Maldey, Haile and Shumye 2014; Nagata et al. 2014; Sadler et al. 2012). In Ethiopia (Sadler et al. (2012) found a very high (71%) rate of program incompleteness while a similar Ethiopian study found a very low (6%) rate (Maldey, Haile and Shumye 2014). The study by Maldey, Haile and Shumye (2014) used systematic sampling which might have contributed to an underestimation of program incompleteness. A relatively low percentage (23%) of adults living with HIV did not complete the program in a study conducted in sub-Saharan Africa (Kenya and Uganda) (Ahoua et al. 2011). Similarly, in another study in Kenya, low (11.9%) program incompleteness was reported among adult participants enrolled in a nutritional program (Nagata et al. 2014). Presence of severe acute undernutrition, severe food insecurity at baseline, and HIV clinical stages III and IV were associated with program incompleteness (Ahoua et al. 2011; Sadler et al. 2012) (Table 2.8).

There has been limited research on the extent of program incompleteness and its determinants in HIV positive children in nutritional programs. However, a study in Malawi reported that 22.7% of HIV positive and 14.2% of HIV negative children failed to complete the nutritional program (Bahwere et al. 2008). Another study from Senegal reported 21% withdrawal from a nutritional program among HIV positive children but the evidence was inconclusive because of the small sample size (Cames et al. 2016) (Table 2.8). Furthermore, a study conducted in Ethiopia among acute severely undernourished HIV negative children admitted to a hospital nutrition rehabilitation unit found 9% of children did not complete the program (Jarso, Workicho and Alemseged 2015). There is no evidence about the factors that affect withdrawal from nutritional programs in HIV care in children. There is also little evidence on the demographic and socioeconomic, clinical and immunological determinants of program incompleteness in HIV care settings for adults or children.

Table 2.8: Nutritional program incompleteness and its determinants in sub-Saharan Africa

Authors	Magnitude program incompleteness	Country	Determinants			
	Adults					
Ahoua et al. (2011)	23%	Kenya and Uganda	Presence of severe acute undernutrition, severe			
Sadler et al. (2012)	71%	Ethiopia	Food insecurity at baseline			
Nagata et al. (2014)	12%	Kenya	Clinical stages III and IV Pre-ART and on ART			
Maldey, Haile and Shumye (2014)	6%	Ethiopia	<6months Attending nutritional therapy at hospital Presence of tuberculosis (TB) and other co-infections at enrolment 			
Children						
Bahwere et al. (2008)	22.7%	Malawi	No evidence			
Cames et al. (2016)	21%	Senegal				

2.7.3 Program non-response

Non-response is defined as not achieving BMI>18.5kg/m² after program completion in two consecutive visits or not achieving BMI>20 kg/m² (Ahoua et al. 2011; Sadler et al. 2012). Studies in Ethiopia have demonstrated high non-response rates, with Sadler et al. (2012) reporting 58% and Maldey, Haile and Shumye (2014) reporting 30%. Meanwhile, a low (13.5%) non-response rate was reported in a study in Kenya and Uganda among adults living with HIV (Ahoua et al. 2011). It is speculated that the Ethiopian study (Sadler et al. 2012) was conducted at the initial stages of the nutritional program which may have contributed to the high magnitude of non-response. This may be related to health providers' experience and inadequate knowledge about the program among people living with HIV (Table 2.9).

Very few studies have examined the determinants of non-response among adults living with HIV enrolled in nutritional programs (<u>Bahwere et al. 2011</u>; <u>Sadler et al. 2012</u>). One study found the presence of opportunistic infections contributed to ineffectiveness of the nutritional program (<u>Ahoua et al. 2011</u>). Furthermore, severe and acute undernutrition, having low CD4 count at enrolment and attending the nutritional program in a hospital setting were associated with higher rates of non-response in HIV care (<u>Sadler et al. 2012</u>). On the other hand, severe food insecurity was associated with a decrease in likelihood of non-response especially among moderately undernourished patients (<u>Sadler et al. 2012</u>), but this study did not undertake a comprehensive examination of demographic and socioeconomic, immunologic and clinical, nutritional and anthropometric issues that may affect program non-response.

There were limited studies about non-response and its determinants in children living with HIV. According to a study by Rollins et al. (2007), age and days with diarrhoeal disease were contributors to non-response in children living with HIV. In another study in Tanzania, children with parents of high economic status were less likely to be non-respondent (WFH<-2SD), while those who reported food insecurity and hunger were more likely to be non-respondent (Sunguya et al. 2012). Similarly, a study conducted in Ethiopia among HIV negative children found non-response rates of 30% in those who received CSB and 24% among those who received RUTF. Non-response was not related to child's age, sex, initial weight or health status (Karakochuk et al. 2012). However, there is no evidence about the factors that affect program non-response among undernourished children living with HIV.

 Table 2.9: Nutritional program non-response and its determinants in sub Sharan Africa

Authors	Magnitude of program non- response	Country	Determinants		
Adults					
Ahoua et al. (2011)	13.5%	Kenya and Uganda	Severely undernourished at enrolment		
Bahwere et al. (2011)	37%	Malawi	Low CD4 at enrolmentAttending nutritional therapy in		
Sadler et al. (2012)	58%	Ethiopia	hospital compared with primary health care centres		
Maldey, Haile and Shumye (2014)	30%	Ethiopia	nealth care centres		
Children					
Rollins et al. (2007)	Not estimated	South Africa	Younger age		
Sunguya et al. (2012)	Not estimated	Tanzania	More days of diarrhoeal diseaseFood insecurity and hunger		

2.7.4 Relapse of undernutrition

Maintenance of nutritional status after nutritional recovery is an important indicator of the effectiveness of nutritional programs in HIV. One study in Ethiopia reported a 20% rate of relapse of undernutrition after nutritional recovery in adults living with HIV (<u>Sadler et al. 2012</u>). This study did not identify the determinants of relapse of undernutrition because of the short follow-up period, which was up to six months after nutritional recovery. Thus, there is no adequate evidence on the magnitude and determinants of relapse of undernutrition in HIV care after nutritional recovery.

Similarly, there have been no studies examining the magnitude of relapse and its determinants in children living with HIV, but studies have examined relapse among HIV negative children (Chang et al. 2013; Somassè et al. 2016). In Burkina Faso, (Somassè et al. 2016) reported a 15.4% relapse rate after nutritional recovery among HIV-negative children treated for moderate undernutrition. According to these authors, children who were discharged with MUAC less than 125 mm were more likely to relapse, while children who were vaccinated and those who consumed oil or fat in the 24 hours before interview were less likely to relapse (Somassè et al. 2016). Another study found HIV negative children treated for moderate undernutrition were at risk of relapse of undernutrition after nutritional recovery (Chang et al. 2013).

Overall, there was little evidence about the baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics that may predict relapse of undernutrition after nutritional recovery among adults or children enrolled in nutritional programs.

2.7.5 Barriers to and facilitators of utilisation of nutritional programs

Utilisation of nutritional programs in HIV care is crucial for program effectiveness, but adherence to programs is sub-optimal (<u>Bahwere et al. 2011</u>; <u>Kebede and Haidar 2014</u>). For example, <u>Kebede and Haidar (2014)</u> found that only 36% of people living with HIV adhered to the RUTF in Ethiopia. In Malawi, a higher proportion of adults living with HIV who were adherent to the nutritional program achieved nutritional recovery than non-adherent individuals (<u>Bahwere et al. 2011</u>). However, these studies only examined adherence to nutritional support and not the full package of the nutritional program including nutritional counselling.

According to various studies, issues related to nutritional support such as taste and side effects affected the utilisation of the nutritional program (<u>Dibari et al. 2012</u>; <u>Olsen et al. 2013</u>). The barriers varied by the type of nutritional support, the context in which it was used, and where the nutritional program was implemented. Some health system related factors such as lack of adequate training of health providers and inappropriate counselling were also reported as factors hindering the utilisation of nutritional programs (<u>Dibari et al. 2012</u>). Although evidence on the barriers to and facilitators of utilisation of nutritional programs in HIV care settings was limited, a number of factors emerged from the literature as explained below.

HIV related stigma and discrimination

Some studies have identified the role of HIV status non-disclosure as a key factor to ART non-adherence (Coetzee, Kagee and Vermeulen 2011; Ware et al. 2009) and this could be a similar concern for HIV patients provided with bulky portions of RUTF or other types of nutritional supports. Evidence from African countries suggests stigma experienced by patients as a result of using or transporting bulky containers of nutritional support acted as a barrier to program utilisation (Dibari et al. 2012; Hussien et al. 2015; Kebede and Haidar 2014; Olsen et al. 2013). However, none of the above studies adequately looked at the mechanisms by which the nutritional programs in HIV care contributed to HIV stigma and discrimination.

Food insecurity

As presented in **sub-section 2.3.2**, there is extensive evidence on the level of food insecurity among people living with HIV. Household food insecurity was the most common cause of wasting among people living with HIV in sub-Saharan Africa (Musumari et al. 2015).

Few studies have examined the role of food insecurity in nutritional programs in HIV care. Bahwere and his colleagues found widespread food insecurity among participants enrolled in a nutritional program in HIV care and the poorest response to the program was observed among participants in the tertile with worst food insecurity (Bahwere et al. 2011). A study conducted in Ethiopia among moderately undernourished people living with HIV reported that those with severe food insecurity were less likely to be non-respondent (Sadler et al. 2012). However, these findings were not replicated by other studies and there was no adequate evidence about how food insecurity influences nutritional programs in HIV care.

Sharing and selling of the nutritional support

Sharing nutritional support with other family members was identified as one challenge to program utilisation (<u>Hussien et al. 2015</u>; <u>Sadler et al. 2012</u>). <u>Hussien et al. (2015</u>) found sharing practice was related to a lack of understanding of program purpose, such as considering the nutritional support to be part of the family's diet, and sharing was more common in poor households and participants with children. Moreover, food sharing may be a group norm in some cultures (<u>Gedrich 2003</u>). There are contrasting findings from studies about sharing of nutritional support and food insecurity in Ethiopia. For instance, <u>Olsen et al. (2013)</u> indicated that food insecurity was not related to sharing of nutritional support by participants while <u>Hussien et al. (2015)</u> found problems of sharing because of food insecurity. However, none of the studies provided a detailed examination of the impact of food insecurity on nutritional programs.

The sharing practices among caregivers of children with HIV was examined in a study in Ethiopia. Caregivers experienced a dilemma about whether to share the nutritional support with other family members or to sell it to meet other economic or food needs of the family (Tadesse et al. 2015). Moreover, the use of and adherence to the nutritional support in HIV negative undernourished children was dependent on the knowledge and acceptance of their caregivers. It is not clear whether similar factors applied to caregivers of HIV-positive children. Generally, there was no adequate evidence about the multilevel issues that influence utilisation and challenge the success of nutritional programs in HIV care. Selling the nutritional support was another challenge in HIV care settings, with one study revealing that 11% of participants sold the nutritional support provided to them (Kebede and Haidar 2014), and there were reports of the availability of nutritional support in markets (Hussien et al. 2015).

Social factors

There was limited evidence about the impact of social factors on nutritional programs in HIV care in sub-Saharan Africa. In Ethiopia Olsen et al. (2013) found religious fasting was not a concern in nutritional programs because participants considered the nutritional support as medicine where social norms related to fasting were not applicable.

Other social factors such as social networks and family support assisted utilisation of HIV care, especially ART care (Roura et al. 2009), but there was no evidence about the impact of such factors on the utilisation of nutritional programs in HIV care. Social and cultural factors such as traditional healing and religious issues have been identified as potential barriers to ART adherence (Kagee and Delport 2010) but there was very limited evidence regarding the effects of various social and cultural factors on nutritional programs in HIV care settings.

Operational and programmatic factors

Operational and programmatic related challenges vary by program and country of implementation and context. For instance, in Ethiopia, program related challenges included issues related to sustainability and problems of alignment between ART and nutritional programs appointment dates (<u>Hussien et al. 2015</u>). Another study from Kenya reported that lack of appropriate counselling and transportation arrangement for frail patients were challenges related to program design (<u>Dibari et al. 2012</u>). Family centred programmatic approaches were reported to be important in improving use of HIV care services, mainly ART (<u>Van Winghem et al. 2008</u>) but there was no evidence on the effects of such programmatic factors on nutritional programs in HIV care.

In conclusion, while a range of social, operational and programmatic issues can contribute to a better program performance or constrain program effectiveness, there is no adequate evidence that examines these issues in-depth.

2.8 Summary and the evidence gap

Improving the nutritional status of people living with HIV must be based on sound scientific evidence, while consideration of local resources, programmatic and clinical experience are all crucial to enhancing longevity and quality of life. People living with HIV are vulnerable to undernutrition and in response to the extent and magnitude of this problem, nutritional programs have been introduced as a crucial component of HIV care, treatment and support services in sub-Saharan Africa. Nutritional programs in sub-Saharan Africa vary in terms of enrolment criteria, duration and nutritional supports used despite their shared goal of improving nutritional status, ART treatment outcome and overall wellbeing. Nutritional assessment, counselling and provision of prescribed foods for undernourished people living with HIV are now part of many nutritional programs in HIV care in sub-Saharan Africa including in Ethiopia.

There is adequate evidence of the role of nutritional programs in improving nutritional status (improved weight or BMI) and adherence to ART, with nutritional support involving RUTF appearing to be more beneficial than other food supports in terms of the magnitude of gains in BMI and weight. However, nutritional support has not been related to improved survival and reduced mortality.

In sub-Saharan Africa, nutritional programs were characterized by low recovery, program incompleteness and non-response. There was limited evidence demonstrating individual demographic and socioeconomic characteristics related with nutritional recovery but the evidence on the role of some clinical and nutritional characteristics on nutritional recovery was mixed.

Moreover, nutritional programs in HIV care were characterized by high program incompleteness, with the highest levels of incompleteness seen in Ethiopia. Several studies identified that baseline nutritional status and advanced WHO clinical stage (III and IV) were related to program incompleteness. However, no studies conducted a comprehensive examination of the demographic and socioeconomic, immunological and clinical, nutritional and anthropometric determinants of nutritional programs in HIV care settings. In addition, there is no evidence on the magnitude of program incompleteness and its determinants among children living with HIV.

Despite variations, the literature has shown a high level of non-response to nutritional programs, with Ethiopia being one of the countries with the highest rate of non-response. Despite this, there was no adequate evidence demonstrating the demographic and socioeconomic, immunologic and clinical, nutritional and anthropometric determinants of non-response to nutritional programs. Similarly, there was no evidence about the extent of non-response and its determinants among children living with HIV. Research related to nutritional programs for children living with HIV is scant, which may be related to ethical challenges related to research on children. Furthermore, while fewer children than adults are living with HIV, children are more vulnerable to undernutrition, but their lower numbers may also be a reason for the small number of studies.

Very few studies reported the magnitude of relapse of undernutrition in adults and none in children living with HIV. Further, there was no evidence to indicate factors that contributed to relapse of undernutrition, but some demographic and socioeconomic factors have been linked to the relapse of undernutrition in HIV negative children.

A range of challenges to the utilisation of nutritional programs have been identified in the literature. There was evidence of overall low adherence to the nutritional support, but no study examined comprehensive adherence to all components of programs, which include nutritional support and counselling of adults and caregivers in the nutritional program. Factors such as stigma, food insecurity, sharing and selling of the nutritional support were reported as potential barriers to program utilisation. However, the review of literature revealed a lack of strong qualitative evidence to examine in-depth contextual and cultural factors enabling or constraining program utilisation.

This study seeks to address these evidence gaps. It was conducted in an ongoing outpatient HIV treatment and care program that has not been comprehensively examined. In addition, the study also includes nutritional outcomes for undernourished children living with HIV, a clear gap in the literature. The study involves a systematic investigation of the demographic and socioeconomic, immunological and clinical, nutritional and anthropometric determinants of nutritional outcomes of adults and children living with HIV enrolled in a nutritional program in Ethiopia. Moreover, it includes the perspectives of program stakeholders, which are largely absent in the literature. It is a mixed methods study, drawing on quantitative and qualitative methods that have rarely been used to investigate these issues. This study adds to the literature by comprehensively examining the challenges to nutritional programs in HIV care settings using contemporary data from contextually diverse areas involving different participants in Ethiopia.

2.9 Theoretical framework(s) underpinning the study

To inform the design, guide the analysis and enhance the interpretation of findings, and improve quality and transferability of qualitative findings, use of theories is fundamentally important (Kelly 2010). In this study, the socioecological model (Bronfenbrenner 1979) and social determinants of health model (WHO Commission on Social Determinants of Health 2008) were used in preference to individual behaviour focused models such as the health belief model (HBM) (Becker 1974) and the information, motivation and behavioural skills model (IMB) (Fisher et al. 2008) that are mainly used to explain individual behaviours. For instance, the health belief model posits that behaviour is determined by a number of beliefs about susceptibility and threats to an individual's wellbeing (Strecher and Rosenstock 1997). The IMB, another individual level behavioural model, posits that if "individuals are well informed, motivated to act and possess the requisite behavioural skills for effective action, they will be likely to initiate and maintain health promoting behaviours and to experiences positive outcomes" (Fisher, Fisher and Harman 2003, p 84). Given the importance of broader community and social contexts for nutritional programs in HIV care settings, the models with a narrow focus on individuals and their behaviour are not able to appropriately explain the complexities of interactions between different factors at different levels. Hence, the socioecological and social determinants of health models provide a broader view and assist in understanding and explaining broader social and contextual factors that influence the effectiveness of nutritional programs in HIV care.

2.9.1 Socioecological Model (SEM):

The socioecological model is a theory-based framework used to understand the interaction of individual and environmental factors that determine health behaviours and outcomes (Elder et al. 2007; Gregson et al. 2001). Bronfenbrenner (1994), argued the importance of environmental factors in shaping human development. Scholars in health related fields, especially health promotion, have extended and applied Bronfenbrenner's thinking on the ecology of human development to determine how social, contexual factors and physical settings shape health related outcomes (McLeroy et al. 1988; Rimer and Glanz 2005; Simons-Morton, McLeroy and Wendel 2012). Health related outcomes are re-oriented as not only limited to individual behaviours but also to other factors related to the individual's previous experience and enviromental, social and cultural factors (Simons-Morton, McLeroy and Wendel 2012). The SEM stipulates the importance of environment in influencing behaviours (Bronfenbrenner 1979). It assumes that health behaviour is multidimensional resulting from overarching interaction of individual, interpersonal, institutional, community and social policy level factors based on the intertwined relationship between the individual and environment (McLeroy et al. 1988). The socioecological model was developed and modified over time. It has been influenced by ecological systems theory (Bronfenbrenner 1979) which focuses on the impact of the environment on child growth and development and views behaviour across various systems.

The SEM helps to explicate the influence of different levels of influence on health behaviours. It rests on the following assumptions (<u>Stokols 1996, p 285-286</u>).

- 1. The physical and social environment is a key determinant of the health and wellbeing of individuals.
- 2. Examining health and its promotion should consider the multifaceted and dynamic nature of individual person's environment.
- 3. Human environment that involves from individual participant to small groups, organisation and big aggregates and groups of people and their complex interaction can be studied at various levels.
- 4. The socioecological model emerged from the concepts and ideas of the system theory.

The five levels of SEM were developed from <u>Bronfenbrenner (1979)</u> systems thinking about the influence of micro-, meso-, and exo- level factors in the environment on child development. The five levels of influence in SEM include individual, inter-individual, institutional, community and policy level factors and the model enables the examination of problems at different levels of influence (<u>McLeroy et al. 1988</u>; <u>Reifsnider, Gallagher and Forgione 2005</u>). Thus, this model recognizes the complex interrelationships between the individual, socioeconomic, sociocultural, institutional and environmental determinants of health behaviours and allows us to understand components of a problem at various levels (<u>Reifsnider, Gallagher and Forgione 2005</u>; <u>Stokols 1996</u>). This study employed the five level version of the SEM model as shown below (**Figure 2.4**) (<u>McLeroy et al. 1988</u>; <u>Simons-Morton, McLeroy and Wendel 2012</u>) which are as follows:

- The individual level factors include individual cognition such as knowledge, attitudes, beliefs and perceptions including concepts of state of mind, for example; locus of selfcontrol, self-concept and self-esteem.
- The interpersonal factors include formal and informal networks which include families, friends, neighbours and co-workers.
- Institutional level factors refer to social institutions such as schools, health institutions
 with formal rules and regulations to run these institutions. Such institutions may have
 incentives, organizational culture and structure, administrative types and communication
 that can positively or negatively influence individual behaviour.
- The community level factors include social networks such as churches, neighbourhoods
 and groups of friends and voluntary associations. Community related factors can be
 considered as the influence of different community level factors on the individual and the
 impact of their interaction.
- Social policy level factors include national, regional and local policy, and interpretation thereof.

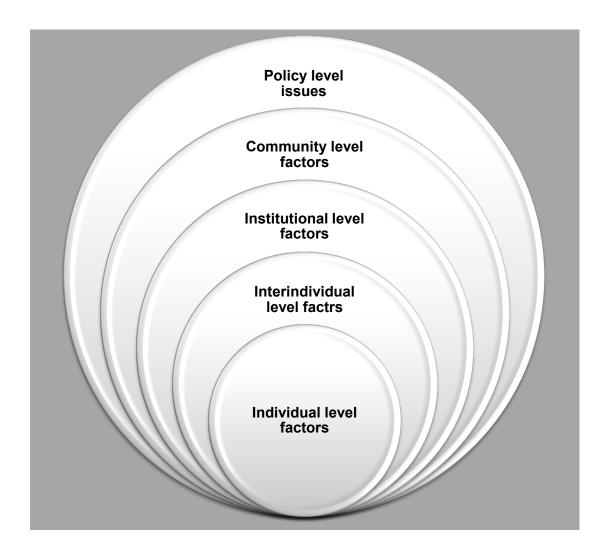


Figure 2.3: Five level socioecological model (Baral et al. 2013; McLeroy et al. 1988).

The socioecological model is important for understanding research, policy and practice gaps by identifying and combining real problems which are not solely explained by individual behaviour because of the interplay of various factors such as biomedical, psychological and social factors which place health in a broader social context (<u>Taruwinga 2014</u>).

The SEM has been employed in studies ranging from health promotion (McLeroy et al. 1988), sedentary life (O'Donoghue et al. 2016), barriers to cervical cancer prevention (Daley et al. 2011), design and evaluation of the effectiveness of interventions (Elder et al. 2007), and to examine the interrelationships between behaviour and environment (Golden and Earp 2012; Newes-Adeyi et al. 2000).

In relation to HIV related research, the SEM has been applied in sexual and reproductive health in people living with HIV, adherence to ART, and acceptability of infant feeding to prevent HIV (Chimphamba et al. 2012; Coetzee, Kagee and Bland 2015; Parker et al. 2011). Chimphamba et al. (2012), used the SEM to identify barriers to sexual and reproductive health utilisation, including individual level beliefs and partner related issues alongside organisational rules such as service hours, established community norms and national reproductive health policies.

The SEM model has also been used to examine nutritional problems of people living with HIV. For example Mahadevan and Ruzsilla (2012) used this model to examine nutritional health outcomes of African American women in the US living with HIV. In addition, SEM has been applied in a study that examined perception, usage and unintended consequences of ready to use food (RUTF) in HIV negative children aged under five years in Ethiopia (Tadesse et al. 2015). In this study, SEM was selected as an appropriate model to guide the study design, data analysis and interpretation of the findings in relation to the challenges of nutritional programs in HIV care settings.

2.9.2 Social Determinants of Health (SDH)

In addition to the SEM, this study also drew upon the Social Determinants of Health (SDH) model (**Figure 2.5**) where the impact of demographic and socioeconomic factors such as employment, educational status and residence (urban–rural) on nutritional programs are further explained.

According to the <u>WHO Commission on Social Determinants of Health (2008, p 1)</u> "the poor health of the poor, the social gradient in health within countries, and the marked health inequities between countries are caused by the unequal distribution of power, income, goods, and services, globally and nationally. The consequent unfairness in the immediate, visible circumstances of people's lives-their access to health care, schools, and education, their conditions of work and leisure, their homes, communities, towns, or cities and their chances of leading a flourishing life". <u>Peters et al.</u> (2008) argued that the social determinants of health can be used to explain health inequalities between rich and poor countries, and rich and poor individuals and concluded that poverty is the most important social determinant of health associated with poor health outcomes and early mortality.

The SDH model has been applied in studies focusing on ART adherence and in the areas of HIV. For example, studies focusing on adherence to ART demonstrated the relationship between social determinants such as educational status, employment and income with adherence to ART (<u>Arrivillaga et al. 2009</u>; <u>Peltzer and Pengpid 2013</u>).

In addition, the SDH model has been used in a study of food insecurity and HIV or AIDS (<u>Weiser et al. 2011</u>). According to (<u>Weiser et al. 2011</u>), the factors that influenced food insecurity among people living with HIV included structural factors such as flooding and drought; socioeconomic factors such as poverty and access to education; and social factors such as gender inequality and HIV-related stigma. Another study from Uganda which applied the SDH model also found lack of social support and internalized stigma as important social determinants of food insecurity among adults living with HIV (Tsai et al. 2011).

However, there has been no study so far that applied the social determinants of health approach to examine the challenge of nutritional programs in HIV care settings. This study draws upon the SDH model to supplement the SEM, mainly in the interpretation of findings (**Figure 2.5**).

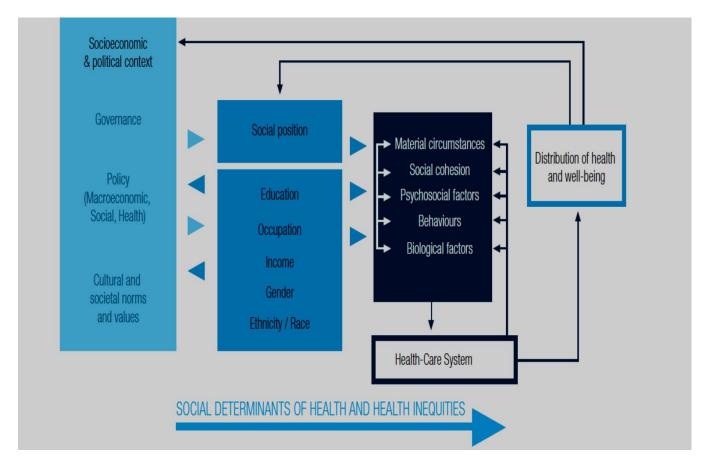


Figure 2.4: Social determinants of health model, source (<u>WHO Commission on Social Determinants of Health 2008</u>).

CHAPTER 3: STUDY METHODOLOGY

Introduction

This chapter elucidates the study setting, overall study methodology and methods of data collection including sampling, recruitment, sources of data and data analysis strategies. The chapter starts with a description of the research setting including the geographic and service related characteristics of the study sites. In the second section, the study methodology and its philosophical foundations is presented in detail. In the third section, methods employed in the quantitative retrospective study (Aims 1 and 2) such as sampling and sample size, data collection procedure, variables, methods of data management and analysis are described. The fourth section presents methods for the qualitative component of the study including selection and recruitment of study participants, data collection procedure, coding and data analysis process (Aim 3). The researcher's reflexivity is presented in the fifth section. The final section describes the ethical considerations and approvals in relation to this PhD study.

3.1 Research setting

This study was conducted in three purposively selected hospitals in Tigray region, Ethiopia:

- Mekelle hospital is in Mekelle City, the capital of Tigray regional state, located 761 km north of Addis Ababa.
- Lemlem Karl hospital is in Maychew town located in the southern Zone of Tigray regional state, the biggest zonal town located 643 km north of Addis Ababa.
- Shul hospital is in Shire Endaslassie in the north-western Zone of Tigray regional state which is located 1023 km north of Addis Ababa (**Figure 3.1**).

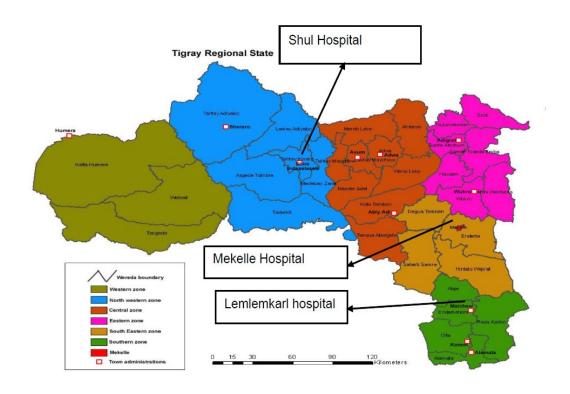


Figure 3.1: Administrative map of Tigray regional state by zone and location of the study hospitals, northern Ethiopia (source: OCHA).

The catchment population for these hospitals is estimated to be two millions. Mekelle hospital has the highest catchment population of approximately more than one million. The estimated catchment population for Lemlem Karl and Shul hospitals are approximately half a million each. Mekelle hospital is the largest hospital in terms of patient load and turnover. According to an unpublished Tigray Regional Health Bureau annual report (2015/2016), total annual outpatient visits to Mekelle hospital were 221,251 individuals in the year, almost twice the number of outpatient visits to the other two hospitals (98,533 and 96,686 individuals per year in Shul and Lemlem Karl hospitals respectively). All three hospitals have been providing comprehensive HIV services since 2003.

In each study hospital, HIV care is provided in a separate department that includes a 'card room' for patient records, an outpatient department to refill ART and treat opportunistic infections, and an ART pharmacy. These outlets provide services to people living with HIV on ART and pre-ART. The total number of staff delivering HIV care in the three hospitals is 45, with approximately 20 in Mekelle hospital 15 in Lemlem Karl hospital and 10 in Shul hospital.

According to the unpublished Tigray Regional Health Bureau annual report (2015/2016), the three study hospitals cover 22% of the total number of people living with HIV who have ever started on ART in the region (**Table 3.1**).

Table 3.1: HIV service indicators among people living with HIV in the three hospitals

Indicators	Name of hospitals			Total	
	Mekelle	Lemlem	Shul		
		Karl			
Ever started on ART	6795	2411	2350	11,556	
Number of newly**	170	123	95	396	
enrolled in pre-ART					
(adults and children)					
Currently* on ART	4201	1403	1477	7081	
Number of children on	304	64	55	423	
ART					
Number of people	130	429	98	657	
nutritionally assessed					
and found to be					
clinically					
undernourished					

^{*}current refers to individuals started on ART up-to June 2016.

In the study hospitals, free HIV testing, and counselling is provided as provider-initiated HIV testing and counselling (PITC) (health provider initiates for clients) in all outpatient and inpatient departments, maternal and child health clinics. HIV positive clients are linked to the HIV care clinic for their HIV treatment, care and support services (**Figure 3.2**).

All the study hospitals provide a range of comprehensive HIV services. These include:

- ✓ Pre-ART HIV services,
- ✓ ART service
- ✓ Nutritional assessment and counselling
- ✓ Nutritional support for undernourished people living with HIV
- ✓ Management of opportunistic infections
- ✓ Other services such as social support and ART adherence counselling

^{**}Newly refers to individuals enrolled in the year September 2015 to August 2016.

HIV services are provided regularly during follow-up visits. New patients who are screened HIV positive are linked to the HIV care clinic which includes pre-ART follow up, ART initiation, and nutritional assessment and counselling. Moreover, HIV patients enrolled in HIV care are regularly monitored for their clinical and immunological improvements using CD4 counts and other clinical parameters. In addition, counselling about ART adherence, side effects, treatment of opportunistic and other infections, HIV testing and counselling are part of the HIV care service provided in the study hospitals.

In terms of nutritional assessment and counselling, for all clients on ART or pre-ART nutritional status is assessed by using Body Mass Index (BMI), mid upper arm circumference (MUAC) or weight for height (W/H) depending on the age of the participants at each appointment date. Clients classified as undernourished are then provided with specialized therapeutic or supplementary foods and nutritional counselling for a period of three to six months (**Figure 3.2**).

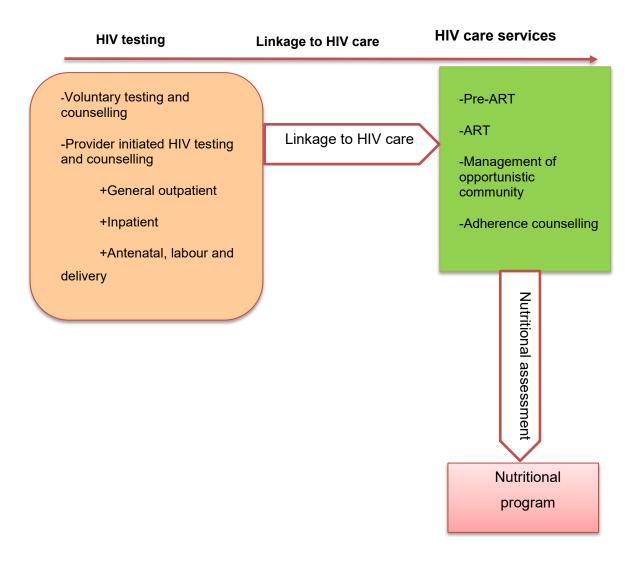


Figure 3.2: Flow chart of HIV testing, linkage and care in the study setting.

3.2 Methodology

"Methodology involves analysis of the assumptions, principles, and procedures in a particular approach to inquiry" (Schwandt 2014, p 195). "Methodology is embedded in the ontological and epistemological assumptions underlying the research question" (Hennink 2011, p 12). Generally, methodology includes the methods, which are the mechanisms and procedures used by investigators to answer a research question, plus philosophical issues such as how reality is conceptualised (Bazeley 2013; Teddlie 2009).

Based on ontological, epistemological and methodological differences, the positivist (quantitative) and the interpretive (qualitative) paradigms are the two main approaches applied by the majority of investigators (Hennink 2011). The two paradigms are considered as distinct and completely divergent (Hennink 2011), but mixed methods has emerged as a third paradigm which brings these two schools of thought together by combining them, using sound methodological and philosophical assumptions. In this way, the positivist and interpretive paradigms are used together to complement each other to address existing problems (Teddlie 2009) drawing on pragmatic epistemology, realist ontology and mixed methods methodology (Teddlie 2009). These three paradigms are discussed and presented below in relation to the research questions in this thesis.

3.2.1 Quantitative (Positivist paradigm)

"The positivist paradigm assumes that reality consists of facts and that researchers can observe and measure reality in an objective way with no influence of the researcher on the process of data collection" (Hennink 2011, p 14). Positivist researchers generate knowledge based on cause and effect by relying on a limited number of factors measured objectively (Creswell 2007). The epistemological position of a positivist paradigm is that the researcher is an independent and external evaluator in the process of producing knowledge (Hennink 2011). According to the positivist paradigm, it is possible to obtain "the truth through valid knowledge production" (Braun and Clarke 2013, p 29).

Positivists usually build on an existing theory to formulate and test a hypothesis (<u>Teddlie 2009</u>). In addition, it is believed there is a single reality or truth that can be discovered using the same methods and instruments as per the positivist paradigm (<u>Creswell 2007</u>). However, the positivist paradigm is criticised for its assumption of objectivity and neglecting the role of the researcher in the process of research, such as the interaction between the researcher and research participants (<u>Hennink 2011</u>). This study involved subjective experiences of program stakeholders in the nutritional program in HIV care and findings in this study also included the researcher's interpretation of the data, which is beyond the scope of the positivist paradigm.

3.2.2 Qualitative (Interpretive paradigm)

"Most qualitative research draws on an interpretative orientation that focuses on the complex and nuanced process of creation and maintenance of meaning" (<u>Liamputtong and Ezzy 2005, p 2</u>). According to the interpretive paradigm, there is more than one truth linked to the context or setting where the data is interpreted (<u>Braun and Clarke 2013</u>). The interpretative paradigm posits reality as "socially constructed as people's experience occur with in social, cultural, historical or personal contexts" (<u>Hennink 2011, p 14</u>). In qualitative research, reality or truth is dependent on context and human experience. This means reality or truth varies by time and context, so the context and mechanisms of knowledge generation are dependent on what is possible to be known (<u>Braun and Clarke 2013</u>).

According to the interpretive paradigm, "knowledge is perspectival and therefore a singular, absolute truth is impossible" (Braun and Clarke 2013, p 29). The interpretive paradigm also stands against the assumption that the researcher is value free. Instead, researchers play a crucial role in the process of data collection and interpretation of results (Hennink 2011). There is no single methodology in interpretive paradigms, but different qualitative studies employ different mechanisms of data collection, analysis, role of the researcher in the research and the relationship of the researcher with research participants (Braun and Clarke 2013). The current study also used quantitative data which is not appropriate with in this paradigm.

3.2.3 Mixed methods (Pragmatic paradigm)

According to <u>Tashakkori and Creswell (2007, p 4)</u> "mixed methods is a research paradigm in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a paradigm of inquiry". This has also been termed a 'pragmatic paradigm'(<u>Teddlie 2009, p 23</u>). A mixed methods design assumes that "the research question drives everything" (<u>Teddlie 2009, p 23</u>) and has its own philosophical foundations, methodology and methods (<u>Creswell 2007</u>). Moreover, a mixed methods paradigm also brings together the positivist and interpretive paradigms and focuses on the research question as the most important factor in determining the research paradigm (<u>Tashakkori and Creswell 2007</u>). While people have used a variety of methods together for some time, mixed methods as a special research approach is a relatively new and popular alternative to understand multifaceted problems (<u>Teddlie 2009</u>).

In a mixed methods paradigm, knowledge encompasses both subjective and objective views depending on the research question, where pragmatists believe that "epistemological issues exist in a continuum rather than on two opposing views" i.e. positivist or interpretive paradigms (Teddlie 2009, p 90–87). The most important assumptions in mixed methods study are that it a) considers personal value systems b) applies what fits best to address the research problem, and c) focuses on researches that has important societal impacts (Teddlie 2009). In a pragmatic paradigm, truth or reality is "normative" and neither the positivist nor interpretive paradigms are best on their position about truth or reality. Instead, truth in mixed methods is "what works best" (Teddlie 2009, p 92). In pragmatism, choice of methods (positivist, interpretive or pragmatism) is dictated by the existential research questions (Teddlie 2009).

In mixed methods, the relationship between the quantitative and qualitative phases of study could be triangulation, embedded, explanatory or exploratory designs (Creswell 2012). In triangulation design, researchers apply the qualitative and quantitative approaches in parallel (Creswell 2012). In embedded mixed method design, one method (either qualitative or quantitative) is used as the foundation while the other approach is used as secondary (Creswell 2012). In explanatory designs, the qualitative results are used to explain quantitative findings while in exploratory design, the qualitative findings are used to develop a research question for quantitative investigation. Both explanatory and exploratory designs are two phase designs (Creswell 2012).

This PhD thesis employed a mixed method study design to address the study aims (**refer to Chapter One**). Mixed methods were particularly appropriate to understand the complex interplay of challenges in the nutritional program in HIV care settings. The challenges in nutritional programs in HIV care settings included examining the determinants of nutritional outcomes and the contextual issues that influence utilisation of nutritional programs. Furthermore, <u>Teddlie (2009)</u>, indicated that the use of mixed methods also enables an in-depth understanding by mixing different types of information and offers an opportunity for a range of divergent views.

The relationships between the quantitative and qualitative approaches in this thesis was triangulation design where the quantitative and qualitative approaches were conducted in parallel (<u>Creswell 2012</u>). The quantitative and qualitative approaches were equally important and combined during the interpretation of findings (**Figure 3.3**).

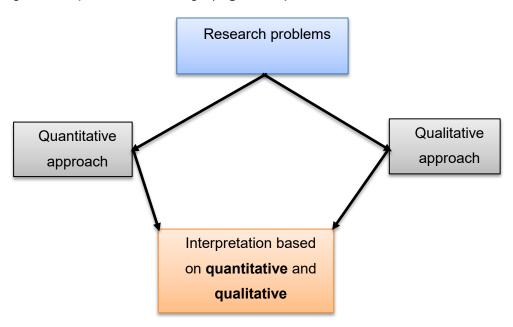


Figure 3.3: Flow chart showing the triangulation design of the relationship between the quantitative and qualitative study. Source: (<u>Creswell 2012, p 63</u>).

To address Aims 1 and 2 (**Chapter One**) a quantitative retrospective cohort study was used to determine the pattern and correlates of nutritional outcomes of adults and children living with HIV ever enrolled in a nutritional program. Demographic and socioeconomic immunological and clinical, nutritional and anthropometric data were collected from chronic HIV and nutritional program databases from the three selected hospitals (Figure **3.1**). To address Aim 3 (**refer to Chapter One**), a qualitative approach was used to explore, identify, explain and understand the barriers and facilitators of program utilization from the perspectives of program stakeholders. Challenges related to the nutritional program were explored in relation to the program design and implementation, sociocultural factors, health service and food support as well as health system related challenges (**Table 3.2**).

Table 3.2: Research design, data collection techniques and methods of analysis

Studies	Research design	Study population	Data collection techniques	Methods of analysis
Aim 1: correlates of nutritional outcomes for adults living with HIV	Quantitative retrospective cohort study	Adults living with HIV in chronic HIV care ever enrolled in the nutritional program (≥15⁴ years of age)	Secondary data retrieval from HIV/AIDS chronic care and nutritional program databases	Descriptive statistics, and logistic regression and Cox regression to identify the correlates of nutritional program outcomes
Aim 2: correlates of nutritional outcomes of children living with HIV	Quantitative retrospective cohort study.	Children living with HIV in chronic HIV care ever enrolled in nutritional programs (6 months –14.99 years)	Secondary data retrieval from HIV/AIDS chronic care and nutritional program databases	Descriptive statistics and logistic regression to identify the correlates of nutritional outcomes
Aim 3: barriers to and facilitators of use of nutritional program identified by program stake holders	Qualitative study	Adults and caregivers of children living with HIV and health providers and program managers	One-on-one in- depth interview	Framework thematic analysis

Assumptions: All classifications and categorization of nutritional outcomes for people living with HIV who were enrolled in nutritional programs were considered as correct and precise. The study was unable to assess the accuracy and precision of anthropometric diagnosis and classification of nutritional outcomes and it considers the outcomes indicated in log books as correct and acceptable measurements.

⁴ Medically, <15 years is considered as child and ≥15 years is considered as adult.

3.3 Quantitative retrospective study

3.3.1 Sampling, population, and sample size

The initial intention of the researcher was to undertake this study in structurally diverse study settings including hospitals and primary health care centres to enable comparison of the challenges for nutritional programs in different HIV care settings. However, a range of issues led to the exclusion of primary health centres. These included accessibility in terms of transport availability and costs, and feasibility in terms of cost of the study. In addition, most health centres started nutritional programs and other HIV services more recently than hospitals. This created difficulties in terms of comparability of the data. As a result, primary health care centres were excluded from the study.

Five hospitals were initially purposively selected with an assumption that they had electronic data for five years (2010–2015). It was thought that the use of electronic data would minimise data collection time and improve data quality. However, after the initial assessment of hospital databases, it was found that there was a lack of data quality and adequacy. Specifically, the datasets only contained a small number of indicators, such as the number of people living with HIV who were on ART and pre-ART and who received nutritional support. The data related to the nutritional program contained aggregated numbers of participants who were clinically undernourished and received the nutritional support, rather than individual patient records. Variables essential for answering the research objectives, such as demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics were not included in these electronic databases. Therefore, a decision was made to use paper-based records that included the necessary data to address the objectives. However, the time and cost of manually retrieving the six years of data from paper records from five hospitals was prohibitive and it was therefore decided to reduce the number to three purposively selected hospitals (**Figure 3.1**).

The original five hospitals were selected for the following reasons:

- Better capacity in terms of data collection, storage and completeness.
- Provision of HIV treatment, care and support services since 2003.
- Cover a significant portion of people enrolled in HIV care in Tigray region (<u>Tigray Regional</u> Health Bureau 2015).
- Easy access and feasibility for data collection.
- The researcher's prior work experience and familiarity with the areas and an existing support network that could play a role in facilitating data collection.

The final three hospitals were selected according to the following criteria:

- Considering the distance from where the health service was managed, coordinated and organised (the regional health bureau).
 - ✓ The health service was managed and coordinated from Mekelle hospital while Lemlem Karl and Shul hospitals were located far from the central office.
- Minimising the inter hospital transfer and double counting of the study participants in the nutritional program because the hospitals were located far away each other.
 - ✓ Shul and Lemlem Karl hospitals were relatively remote compared with Mekelle hospital

All paper-based records for people living with HIV enrolled in the nutritional program from November 2010 to February 2016 were collected. Data abstraction was conducted from 11th March 2016 to 8th July 2016. Accordingly, records for a total of 1757 adults and 236 children living with HIV were retrieved.

Inclusion and exclusion criteria

Inclusion: All records for people living with HIV ever enrolled in the nutritional program from November 2010 to February 2016 in the selected study hospitals were included.

Exclusion criteria: Records with no baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric information were excluded. Records with no nutritional outcome information documented were also excluded. In addition, participants with no Medical Registration Number (MRN), or unique ART number or names were excluded because it was difficult to match the different sources of data. The total number of excluded records was 33, where 21 did not have the MRN or unique ART number or names of the participant while the remaining 12 were excluded because they lacked outcome information. Out of the 33 records excluded, 9 of them were children.

3.3.2 Data collection procedure

The researcher visited the study sites to brief hospital managers about the study, and to deliver letters of support obtained from the Tigray Regional Health Bureau (TRHB) and to the hospital management prior to commencement of data collection. Patient characteristics were abstracted from paper-based nutritional program registers and HIV care hospital databases. A pre-coded data abstraction checklist was prepared based on the nutritional program and ART registration paper-based database to facilitate data abstraction (**Appendix A**). Separate checklists were prepared for adults and children people living with HIV because of slight differences in the information to be abstracted. Three sources of data were used:

- The nutritional program follow-up log book.
- Participants' HIV care follow up including ART and pre-ART care (intake form).
- ART pharmacy database; to address incomplete values identified in the other sources.

Unique ART number and pre-ART numbers were used to match records from different sources. In the HIV care service, these unique numbers are used to track, follow up and identify participants enrolled in HIV care. Baseline demographic and socioeconomic characteristics of participants living with HIV were retrieved from the ART and pre-ART intake forms, medical cards (**Appendix A**), and nutritional follow-up log book. In addition, ART pharmacy databases were used for incomplete values. Variables available in the ART pharmacy database were age, sex and residence and ART regimen of the participants and it was limited to those receiving ART.

Baseline immunological and clinical characteristics were extracted from the ART and pre-ART follow up form and medical card. Nutritional and anthropometric variables were extracted from the nutritional program follow-up log book (**Figure 3.4**). Nine experienced data collectors who were diploma graduates in health management information systems working in the study hospitals were recruited and trained by the researcher to collect the data.

Logbook and intake forms also included the patient's name, unique ART number, and medical registration number (MRN) that were used to access participants' cards. Required data were extracted and cards were returned to their proper places. In all hospitals, participants' names without MRN or unique ART number were searched to get the MRN or the unique ART number in a computer database used in the ART pharmacy to assist us access intake forms or patient cards. A mark was placed in the three sources to avoid double counting of participants.

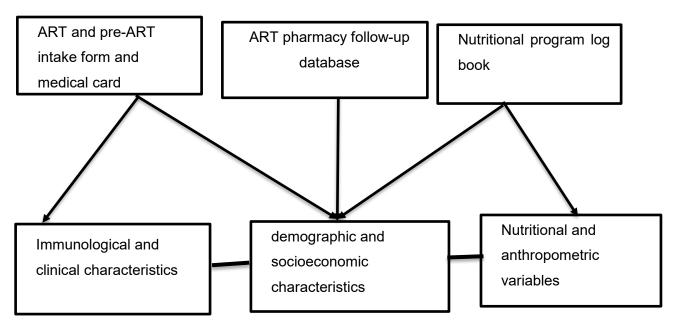


Figure 3.4: Sources of data for each type of variable

3.3.3 Data quality control measures

Training of data collectors

One full day training was provided by the researcher to data collectors in each hospital covering the objectives of the study, methods of data abstraction and meaning of each question in the data abstraction checklist. Data collectors were responsible for collecting and managing the health information in each hospital and therefore were highly knowledgeable about the link between the nutritional program registration book and the HIV care intake forms. During the training, data collectors were reassured that this study was not designed to assess their performance in the hospitals where they work as data managers. After training, data collectors were asked to collect 10 sample data records for quality assessment. Five data collectors were trained in each hospital (three as primary data collectors and two as reserve data collectors). Primary data collectors were selected based on their performance on the first 10 sample records abstracted.

Pre-testing of the study

Pre-testing was done with the 10 records mentioned above in Mekelle hospital with each data collector completing records for one adult and one child. The aim of the pre-test was to examine and determine data collectors' understanding of the content, variables, suitability of the checklist with the sources of data and an estimation of the time taken to complete a single record/ checklist. All data collectors were told to report their concerns about data collection and revision of the checklists was made accordingly. The 10 sample records were entered into the Epi Info™ statistical package for further examination and management. The pre-test information also enabled a modification of the data entry template in light of the feedback and revisions made.

Supervision

The researcher provided supervision during process of the quantitative data collection and responded to queries arising from data collectors. Two percent of the data collected from the logbook and the intake form were verified by the researcher. Each checklist was checked for completeness and consistency at the field site. Inconsistent checklists were sent back to data collectors for further verification of erroneous values and completion of missed values. In addition, all checklists were reviewed for completeness and consistency before data entry.

3.3.4 Data entry and cleaning

A data entry template was designed in Epi Info[™] (CDC 2016) because this program is suitable for preventing entry of erroneous or out of range values. The researcher entered 300 adult and 120 child records to evaluate the smooth running of data entry and undertook a test exporting the data set to SPSS Version 22. Finally, one experienced data clerk was recruited to enter the remaining data after designing and testing of the data entry template in Epi Info[™]. Data cleaning was iterative but the major cleaning was done in SPSS (IBM Corporation 2013) by running frequency tables. Frequency distributions for all variables were generated and checked for inconsistencies and incompleteness and to identify any logical errors to ensure consistency, completeness and other errors during data collection and entry. Inconsistencies and logical errors in the frequency tables were addressed by going back to the checklists. This was facilitated by assigning a number generated in Epi Info[™] to each paper-based checklist to trace back any errors and inconsistencies during data entry.

Missing data analysis

A review of missing data was undertaken, and most cases had negligible missing values (**Table 3.2**). Height at exit, baseline haemoglobin, CD4 count, employment and BMI at exit were the variables with some missing values. Missing values analysis was done by cross tabulation for each variable even for the cases with negligible missing values, using the Little's completely missing at random test by which the means of recorded values of each variable are compared (Little 1988). Thus, the missing values were random or proportionally distributed across all values of the recorded variables (p = 0.63). As such, there was no effect of missing values on our further analysis because the missing values were randomly distributed. Weight, height and BMI at exit were used to verify the nutritional outcomes but not directly included in the analysis.

Table 3.3: Missing value analysis showing the variables with missing values

Variables	Number	Percent	Valid number
	Adults		
Height at exit	292	16.6	1465
Baseline haemoglobin	238	14.2	1441
BMI at exit	171	9.7	1586
Weight at exit	148	8.4	1609
Duration on ART	94	5.6	1585
Employment	43	2.4	1638
Number of sachets	31	1.8	1726
Baseline CD4 count	26	1.5	1653
Family or household size	7	0.7	1750
Duration of stay in the	6	0.3	1751
nutritional program			
Children			
Child's birth order	102	43.2	134
Haemoglobin at baseline	56	23.7	
CD4 at baseline	7	3.0	129

3.3.5 Variables

Dependent variables

The duration of nutritional support was three months for moderate acute undernutrition and six months for severe acute undernutrition. There were five possible nutritional outcomes once a person living with HIV was enrolled in the nutritional program. The outcomes were:

- ✓ Nutritional recovery (graduation),
- ✓ Non-response to the nutritional program,
- ✓ Nutritional program incompleteness (default),
- ✓ Mortality while in the nutritional program, and
- ✓ Relapse after nutritional recovery.

Relapse were considered as a separate outcome and defined as recurrence of undernutrition after declared graduation from the nutritional program.

The dependent variables were redefined as follows for this analysis and relevance to the nutritional program:

Program incompleteness: Program incompleteness included those who defaulted from the program or were lost to follow up before their nutritional outcomes could be assessed.

Program non-response: Program non-response is defined as those who completed the program but did not achieve nutritional recovery according to the program criteria.

Relapse: Relapse was defined as those who completed the nutritional program after nutritional recovery was declared but returned after their weight again dropped below the cut off.

Frequent relapse: Frequent relapse was defined as relapse more than once in the nutritional program after graduation/recovery.

Independent variables

The final data abstraction checklist had sections to extract a range of independent baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics of people living with HIV in the nutritional program.

Demographic and socioeconomic variables: Demographic and socioeconomic characteristics included date at enrolment and exit, age, sex, residence, marital status, educational status, employment, family size and religion and were abstracted from the patient's nutritional program logbook and paper-based intake form in adults. Date at enrolment and exit, age, sex, place of residence, with whom the child was living at enrolment to the nutritional program, mother and father alive or not, mother and father employment, birth order of the child, relationship of the child with guardian, guardian's acceptance of the child, presence of health facility in orphanage for those living in orphanage, school attendance of the child and reason if not attending were abstracted for children (**Appendix A**).

Immunological and clinical variables: These included baseline functional status, WHO clinical stage, CD4 count, haemoglobin level, on ART or pre-ART, ART status, duration on ART if on treatment, cotrimoxazole prophylaxis, presence and type of opportunistic infection. In addition to those variables, ART eligibility criteria were also recorded for children living with HIV (**Appendix A**).

Nutritional and anthropometric information: Anthropometric measurements were taken by service providers for all participants enrolled in the nutritional program at baseline and subsequent visits every month at. All anthropometric measurements at admission and discharge for adults and children living with HIV were abstracted. In addition, nutritional status at enrolment, number of sachets prescribed per day, duration of stay in the nutritional program, outcome of an appetite test and subsequent weight gain was collected. The nutritional outcomes of people living with HIV after enrolment in the nutritional program were collected as indicated in the nutritional program registration book or paper-based database (**Appendix A**).

3.3.6 Data management, preparation and analysis

After completion of data entry, data was exported to SPSS for cleaning and analysis. Before the analysis, recoding, transforming and re-categorization of variables were undertaken as required to facilitate further analysis and interpretation.

Descriptive statistics: Summary statistics using percentages and means were used to summarise and describe characteristics of the study participants. In addition, tables were used to present the descriptive characteristics of participants as below:

- Demographic and socioeconomic characteristics
- Immunological and clinical characteristics
- Nutrition and anthropometric information

Analysis was conducted first to determine the level of program incompleteness. In doing so, default and lost to follow up were merged to create the variable 'program completeness' versus 'incompleteness'. Furthermore, among those who completed, we determined the magnitude of those who became non-respondent despite full attendance for the program's duration.

Relapse of undernutrition after nutritional recovery and frequency of relapse were the other two outcomes determined and described in the analysis. The distribution of the outcome variables (program incompleteness, non-response, relapse of undernutrition after nutritional recovery and frequency of relapse) across different categories of demographic and socioeconomic, immunological and clinical variables, nutritional and anthropometric characteristics were assessed and described accordingly using cross tabulation.

Death and transferred out were two other nutritional program outcomes among people living with HIV enrolled in the nutritional program. However, the researcher was unable to conduct an independent analysis such as cross tabulation because of the small number of patients who died or were transferred out in the study hospitals. The researcher performed analysis of variance in an effort to merge death and transferred out with program incompleteness. Statistically, there was no difference in baseline characteristics such as baseline BMI and nutritional status at baseline among incompletes, death and transferred out. However, it did not appear relevant for the research to merge those who died or were transferred out with those who did not complete the program, so the researcher treated them independently and conducted only descriptive analysis for death and transferred out.

Cross tabulation between death and selected independent variables such as gender, baseline nutritional status, residence and baseline educational status to examine difference in the distribution of death was conducted and there was no statistically significant difference.

Finally, while program incompleteness, non-response and frequency of relapse were dichotomous variables, as was relapse of undernutrition were dichotomous with time element.

Logistic regression analysis (<u>Agresti 2013</u>; <u>2000</u>) was used to identify the determinants of the nutritional outcomes for program incompleteness, non-response and frequency of relapse of undernutrition. Survival and Cox regression analysis (<u>Nikulin and Wu 2016</u>; <u>Vittinghoff 2012</u>) were used to determine the mean time and determinants of first time relapse.

Logistic regression

Logistic regression is a statistical logit model applied to dependent variables with binary outcomes that "will model the chance of an outcome based on individual characteristics" (Sperandei 2014, p 14). "One use of logistic regression is to estimate the probability that an event will occur or that a patient will have a particular outcome using information or characteristics that are thought to be related to or influence such events" (Tolles and Meurer 2016). In logistic regression crude odds ratio (COR) and adjusted odd ratio (AOR) are used to present the magnitude and direction of relationship between the response variable and explanatory variables (Sperandei 2014).

Bivariate logistic regression analysis:

In bivariate logistic regression analysis, statistical association was declared at $p \le 0.3$ (Bursac et al. 2008; Chernick and Friis 2003) to minimise conservative estimation of the determinants of the nutritional outcomes. This enabled the inclusion of marginally significant variables in the logistic regression models. In some cases, variables found to be statistically significant predictors of the outcome variables in previous other studies but with a p value>0.3 in the current study were also included in multivariate logistic regression analysis (Bursac et al. 2008).

The following bivariate logistic regression analyses were conducted:

- 1. Nutritional program completeness (0)⁵ versus incompleteness (1): This analysis examined the determinants of program incompleteness compared with those who had completed at least once, in adults and children, to determine the factors that contributed to program incompleteness. In the bivariate logistic regression analysis, each demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristic was examined for possible statistical relationships. The crude or preliminary relationships between the independent and dependent variables were generated and the COR with 95% confidence interval (CI) was reported. Independent variables with *p*≤0.3 were reported and presented in the bivariate logistic regression analysis table.
- 2. Nutritional program recovery (0) versus non-response (1): This analysis was conducted among those who had completed the nutritional program. Bivariate logistic regression analysis was conducted to determine the crude relationship between the outcomes variables which included recovered versus non-response and the independent variables for adults and children which included baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics. The crude relationship between the outcome and independent variables with p≤0.3 were reported as unadjusted odds ratio with 95% CI in the bivariate logistic regression.
- 3. Frequency of relapse of undernutrition: The statistical relationships between the outcome variable, frequency of relapse of undernutrition and the independent variables were determined only in adults. The outcome variables were dichotomised as relapsed once (0) and relapsed more than once (1). In the bivariate logistic regression analysis, statistical significance was considered at p≤0.3 and unadjusted odds ratio was reported. Because of the small number of children's records collected, we were unable to determine the determinants of frequency of relapse in children living with HIV.

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⁵ This indicates the probability of the event and SPSS recognises 0 as no event and 1 as the event happens.

The assumptions of logistic regression were checked as follows (<u>Alexopoulos 2010</u>) before conducting the multivariate logistic regression analysis.

- Normal distribution: all continuous variables were checked for normality.
- Homogeneity of variance: when comparing one or two continuous variables, the mean (standard variation) of all variables was considered to ensure similar spread.
- Multi-collinearity: a correlation test using Pearson Correlation Coefficient was done for variables measuring the same concepts to assess for correlation (<u>Chernick and Friis 2003</u>; <u>Tu et al. 2005</u>). No variables were correlated in adults or children, but baseline nutritional status was correlated with number of sachets prescribed in adults. For this reason, number of sachets prescribed was removed from the analysis because it was not significant in the multivariate logistic regression analysis when baseline nutritional status was removed. On the other hand, baseline nutritional status was statistically significant when number of sachets prescribed was removed.

Multivariate logistic regression

Finally, separate multivariate logistic regression analyses were conducted to assess the independent relationships between outcome variables including, program completeness versus incompleteness, nutritional non-response versus recovery and frequency of nutritional relapse with the independent variables. Independent variables with $p \le 0.3$ in the bivariate analysis were included in multivariate logistic regression analysis (<u>Bursac et al. 2008</u>; <u>Chernick and Friis 2003</u>). Adjusted odds ratio (AOR) with 95% CI were used to interpret the strength and direction of relationship/association. Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics with p < 0.05 in the multivariate logistic regression were considered as statistically significant (<u>Chernick and Friis 2003</u>).

Cox regression model

Cox regression was used to examine the relationship between the outcome variable relapse of undernutrition and the demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics. Such a regression is appropriate when the outcome variable relates to time to event data or survival data, in this case time to first time relapse of undernutrition (Sedgwick 2013). "The Cox proportional hazard model which is applied for a single binary outcome can be adapted for ordered categorical, unordered categorical, numerical discrete and continuous covariates" (Tai 2014, p 127–128).

Bivariate Cox regression

Relapse of undernutrition: In this analysis the outcome variable was dichotomised as yes for those who relapsed and no for censored (no for those who had not relapsed). Bivariate Cox regression was conducted to determine and compare the presence of crude statistical relationships between the outcome and independent baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric variables in adults. Among the independent variables included in the bivariate Cox regression, statistical significance was declared at $p \le 0.3$. Crude odds ratio with 95% CI was reported for the independent variables found to be statistically significant at $p \le 0.3$.

Assumptions of Cox regression

The proportional hazard model assumes that:

- 1. There is linearity and additivity of predictor variables related to "log hazard" or "log cumulative hazard"
- 2. the "no time by predictor interaction" means the explanatory variables have similar effect on the "hazard function at all values of time" (<u>Harrell 2001, p 468</u>).

Multivariate Cox regression

Multiple Cox regression analysis was conducted to examine the baseline determinants of relapse of undernutrition among adults living with HIV. However, the researcher was unable to assess the determinants of relapse in children because of the small number of children who relapsed. In the Cox proportional hazard model, those who relapsed were considered as an event to identify the determinants of relapse of undernutrition and those who did not relapse up to July 2016 were considered as censored. Baseline demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics with $p \le 0.3$ in the bivariate Cox regression was included in the multivariate Cox regression analysis. In the multivariate Cox regression analysis, statistical significance was declared at p < 0.05. Adjusted hazard ratio with 95% confidence interval was reported to demonstrate the statistical relationship and direction of association between the dependent and independent variables or identify the independent predictors of relapse of undernutrition.

3.4 Qualitative study methods

Qualitative research as a paradigm has been discussed in the methodological foundations of the study in **section 3.2**. Qualitative research is crucial to understand human experience and behaviour. In addition, qualitative studies are important to understand people's interpretation of their actions (<u>Hennink 2011</u>; <u>Rice and Ezzy 1999</u>). In the qualitative component of the study, the views and perceptions of the study participants were investigated.

In addition to people's experiences and actions, the setting where those experiences and behaviours are performed is important in qualitative research (Hennink 2011). Settings allow the researcher to understand and contextualize behaviours, actions or materials in relation to the perspectives of the study participants (Hennink 2011). Settings include the social, economic, cultural and physical contexts that are vital to understand and interpret participants' behaviours and experiences (Braun and Clarke 2013; Hennink 2011). Furthermore, qualitative research is conducted in a setting where the study participants work, live or encounter their experiences or actions which is referred to as "natural world" (Liamputtong and Ezzy 2005, p 4–5) or "natural setting" (Hennink 2011, p 9). Setting or context is vital in the interpretation of people's experience and contributes to the broader and fuller understanding of research participants' perspectives (Hennink 2011; Liamputtong and Ezzy 1999).

According to <u>Brazeley (2013, p 4)</u>, "qualitative researchers focus on observing, describing, interpreting and analysing the way that people experience, act on about themselves and the world around them". The most important characteristics of qualitative research is its dependency on the investigator's understanding and creativity (<u>Liamputtong and Ezzy 2005</u>). Interpretation of qualitative data is influenced by the researcher's experience in terms of social and cultural dimensions (Brazeley 2013).

3.4.1 Selection of study participants (Sampling)

The purpose of qualitative study is to provide an "in-depth understanding" of the problem under investigation based on participants "accounts and rich experience" (<u>Liamputtong 2013, p 14</u>). For this reason, non-probability sampling is the most common sampling technique in qualitative study. Fundamentally, generalization is not the aim of qualitative study. Rather, understanding the nature and interpretative process that existed in people's experiences is the primary objective (<u>Liamputtong and Ezzy 1999</u>).

One of the most common sampling techniques in qualitative study is purposive sampling (Liamputtong 2013). "Purposive sampling aims to select information rich cases for an in-depth study to examine meanings, interpretations, processes and theories" (Liamputtong and Ezzy 2005, p. 46). These cases are "individuals or events or settings from which researchers can learn extensively about the issues under examination". Information rich cases provide more detailed evidence of peoples experiences than "empirical generalisations" (Liamputtong 2013, p. 14). Purposive sampling enables recruitment of participants with greatest potential to provide rich and diverse information relevant to the research problem (Brazeley 2013). Purposive sampling was employed in this study to recruit study participants whereby subjects were selected because of certain characteristics and relevance to the research question.

Compared with quantitative studies, sample size in qualitative studies is small because of the depth of information and differences in experiences (Hennink 2011). In qualitative studies, the quality of evidence in terms of depth and adequacy to answer the research question is more crucial than the quantity of participants (Liamputtong 2013). There are no clearly set guidelines or formulae to determine the number of study participants in a qualitative study but researchers are governed by the repetition of information by the study participants, termed information saturation (Hennink 2011; Liamputtong 2013). Furthermore, other important issues such as type and scope of research question and methods used are also considered in determining the sample size in qualitative study (Liamputtong 2013). Conversely, others have stated the importance of the minimum number of participants ranging from 20–30 individuals (Creswell 2007).

Given the above considerations, the sample size in this specific study involved 48 participants proportional to the study sites and informant groups. Recruitment of study participants ceased when theoretical saturation was achieved. The number of participants enrolled in this study had also fulfilled the recommended minimum sample size as suggested by Creswell (2007).

The three groups recruited in this study and number of participants recruited per hospital is presented below (**Table 3.3**). As indicated above, selection of study participants was based on their relevance to the research questions and included adults and caregivers of children living with HIV, health providers and program managers.

Adult HIV participants

Adults living with HIV enrolled in the nutritional program were eligible to participate in the study because they were directly involved in the nutritional program in HIV care. A total of 20 individual in-depth interviews were conducted with adults (≥18 years of age) living with HIV in the nutritional program at the time of data collection (**Table 3.3**). The total estimated number of participants approached was 60 (**Table 3.3**). During recruitment, heterogeneous sampling was employed to include study participants with various experiences, gender, age, and nutritional outcome if graduated. Potential participants were approached in the clinic waiting room by the researcher at the study hospitals during their regular clinic visit for the nutritional program, ART or other chronic HIV care services. Prior to the interview, the health providers introduced the interviewer (researcher) to adults and caregivers of children living with HIV and the researcher read or gave the introduction letter followed by the consent form for those who agree to participate in the study. The health providers did not know who agreed to participate or not to avoid risk of coercive. Information was provided about the study and an invitation was given in writing or orally to participate in a one-on-one in-depth interview. Depending on the participant's literacy level, written or oral consent was sought.

Caregivers of children living with HIV

The second group of participants was caregivers of children living with HIV. Similar to adults living with HIV, this group of participants was eligible for this study because their HIV positive children were direct users of the nutritional program. In addition, caregivers had close knowledge of the children's experience in the nutritional program and other issues that might affect utilisation. Caregivers of children living with HIV below 15 years of age were identified and approached by the researcher in the waiting room of each hospital during their regular follow up visits. Medically, persons aged under 15 years are considered as children but according to the Ethiopian Family Law and Constitution those aged under 18 years are considered as children (The Federal Democratic Republic of Ethiopia 1995, 2000).

Potential participants were provided with information about the study and given an invitation to participate in an interview session. A total of 45 caregivers were approached with 15 of them accepted to participate. Caregivers has to be at least in their second visit in the nutritional program in order to be included in the study. In addition, caregivers with children who were up to one year after graduation was included to increase the potential participants which was up to six months in the case of adults. **Table 3.3**).

Nutritional program staff (health providers and program managers)

The nutritional program staff were included in the study because of their insight into health system issues in relation to the program and their direct experience in the nutritional program. In addition, health providers have day-to-day interaction with adults, caregivers and children living with HIV enrolled in the nutritional program and so they can potentially provide individual and programmatic level evidence or beyond. A total of 11 in-depth interviews were conducted with health providers working in the HIV clinic who provided nutrition and other HIV services (**Table 3.3**). For a health provider to be eligible for the study, s/he was required to have at least one year of working experience in the HIV clinic to ensure that they had adequate knowledge and experience of the program and variety of patients. In addition, two regional program managers who worked in this role for more than one year were recruited from Tigray Regional Health Bureau (TRHB).

The researcher distributed an invitation letter to all health providers and program managers working in the HIV clinic of each hospital and TRHB respectively specifying the recruitment criteria. The introduction letter containing the researcher's contact details was distributed to all potential participants, 25 in total. In response, those who wished to participate contacted the researcher. Finally, an information sheet and consent form were provided to those who were willing to participate. Interviews were conducted in participants' workplaces.

Table 3.4: Summary of in-depth interview participants by hospital and recruitment criteria

Study Participants	ipants Recruitment Number recruited per hos			ospital	pital Total	
	criteria	approached	Mekelle	Lemlemkarl	Shul	
Adult HIV patients	Enrolled in the nutritional program during the interview, six months since graduated,	60	8	6	6	20
Caregivers of children HIV patients	Enrolled in the nutritional program for at least one visit during the interview or less a year since child graduation	45	6	5	4	15
Health providers	Have been working in the nutritional program for at least one year	25	5	3	3	11
Program managers	Having good knowledge of the program	2	N/A	N/A	N/A	2
					Total	48

3.4.2 Data collection techniques

The most common methods of data collection in qualitative studies are interview and observation (<u>Creswell 2007</u>). Interview methods involve in-depth interviews and focus group discussion interviews. Furthermore, telephone, online and e-mail interviews are considered as extensions of face-to-face interviews (<u>Braun and Clarke 2013</u>; <u>Creswell 2007</u>).

"A focus group discussion is an interactive discussion between six to eight pre-selected participants, led by a moderator and focusing on a specific set of issues" (Hennink 2011, p 136). In focus groups, the interaction between the participants during the group's conversation is fundamental. (Braun and Clarke 2013). However, because of the sensitivity of HIV as an illness and issues in relation to HIV disclosure, stigma and discrimination, in-depth individual interviews were selected as the preferred data collection method for the current study. In addition, in a group setting it is difficult to explore the complex beliefs and practices of an individual person in detail. In addition, some participants in focus groups may agree with other participants' views and be reluctant to express their private experiences because of concerns about anonymity (Hennink 2011; Liamputtong and Ezzy 2005).

In general, an in-depth interview involves a one-on-one, face to face interaction between the participant and the researcher that captures the study participant's thoughts, perceptions, feelings and experience in their own words (<u>Liamputtong 2009</u>). In-depth interviews involve asking participants open ended questions and recording their responses for further transcription, translation and analysis (<u>Braun and Clarke 2013</u>). In-depth interviews were used in this study to gain a detailed understanding of the perspectives of program stakeholders (adults, caregivers and health care providers and program managers) about the challenges of the nutritional program in HIV care.

An interview guide is a sequence of interview questions that guides the process of interviewing (Braun and Clarke 2013). A semi-structured interview guide was used in this study, where similar questions are put to each participant but where the order and wording of questions may vary, and other topics may arise. The interview guide was informed by studies that covered patient related sociocultural, health service and food support related barriers and facilitators of utilisation and other challenges for the nutritional program in HIV care setting. The interview guide was discussed in regular supervisory meetings and further refined based on emerging ideas in the interview process. Because a significant number of study participants had limited formal education, adequate time was given to participants to understand and respond the questions and seek clarification. Interview questions are attached in **Appendix B**.

The researcher who conducted the interviews (Fisaha Tesfay) is male who was born and grew up in the study area and was familiar with local culture, and the interviews were conducted in the local language Tigrigna, in which the researcher and informants were conversant. While some argue that the interviewer should preferably be of the similar age, sex, gender, race, class and sexual orientation as the interviewee (<u>Davis et al. 2009</u>; <u>Manderson, Bennett and Andajani-Sutjahjo 2006</u>; <u>Tang 2002</u>; <u>Williams and Heikes 1993</u>), there is mixed evidence in relation to this (<u>Davis et al. 2010</u>; <u>Kelly et al. 2013</u>).

Significantly, there is no clear evidence about how gender and other characteristics of the interviewer and influence the process of data collection (Moen and Middelthon Anne-Lise 2015). A study by Broom, Hand and Tovey (2009) did not recommend nor demonstrate the most suitable genders for interviewer and interviewee to generate the best evidence. However, the researcher was aware that gender may have been an issue when talking to female participants, but his knowledge of the local culture helped him to address this concern. The researcher took into consideration the cultural sensitivity, and cultural rules in communication with opposite gender. Moreover, his position as an educated researcher may have had an impact on the willingness of participants to discuss some matters. Feasibility of data collection was another concern in this study and this necessitated the researcher to conduct interviews by himself.

The interviews were conducted at a time and venue that was convenient for the study participants. All in-depth interviews were audio recorded. The interviews conducted ranged from 30 to 66 minutes.

All interviews were conducted in the health facility during the regular follow up of HIV patients and caregivers to collect their ART medication, attend the nutritional program or both and at their work place (health facility) for health providers. In-depth interviews for program managers were done in their work place.

Field notes were taken to document the important features of each interview, participant and setting to assist analysis and understanding of data. Field notes can include the interviewers' understanding of the setting and his reflections (Liamputtong and Ezzy 2005). Notes were taken throughout each interview and provided valuable data during analysis and interpretation of findings. For each interview, a summary of important points was made at the end of each session. In addition, notes such as interview time, location, major events in the hospital or surroundings, weather, date of interview, physical setting, feelings of the researcher about the interview and the interviewee were documented which assisted in understanding the context and enhanced the quality of analysis and interpretation. Other observations about the interview location (hospital and HIV service) were also conducted, such as follow up, monitoring, nutritional assessment, waiting time and space, and patient—provider interaction just outside of the room where the service is delivered. Field notes to maintain contextual details were obtained every day during the interview period. The field notes were used during data analysis and interpretation of the qualitative findings and in the overall interpretation for the challenges of nutritional programs in HIV care settings.

With the exception of one caregiver's interview where the child was present, all interviews were conducted in a private room with only the participant and the researcher present.

3.4.3 Rigour (trustworthiness) of the study

"Rigour refers to the quality of the qualitative inquiry and is used as a way of evaluating quality of qualitative research" which is equivalent to reliability and validity in quantitative research (<u>Liamputtong 2013</u>, p 24). Four parameters were used to evaluate the quality of qualitative findings, namely credibility, transferability, dependability and conformability (<u>Liamputtong 2013</u>).

In this study, recruitment of study participants was based on their knowledge and experience of the nutritional program which increases the credibility of our findings. Credibility was also supported by presenting the various views and experiences of participants. Triangulation was another key strategy to improve credibility of the qualitative findings (Braun and Clarke 2013; Liamputtong 2013). "Triangulation is the use of multiple methods, using a combination of methods, researchers, data sources and theories in a research project" (Liamputtong and Ezzy 2005, p 40). This study achieved triangulation of methods, research participants, study settings and theories to ensure credibility of the findings.

Participant and study setting triangulation was achieved by recruiting purposively sampled study participants from adults, caregivers of children living with HIV, health providers and program managers. In addition, the study involved three hospitals located in different settings which also enabled the researcher to understand the challenges for nutritional programs in HIV care. The qualitative data collection process lasted for about five months which assisted the recruitment of diverse groups with different experiences, such as those who have previous experience in the nutritional program and caregivers.

The study also employed two theories (socioecological and social determinants of health models) to guide the process of data analysis and interpretation. The use of these theories allowed the researcher to achieve a broader understanding and interpretation of the findings through theory triangulation. The socioecological model was also used in the design of this study, and in data analysis and synthesis (Bronfenbrenner 1996). Some factors influencing the effectiveness of nutritional outcomes, especially factors hindering program utilisation were better interpreted using the social determinants of health (WHO Commission on Social Determinants of Health 2008).

Another parameter of study rigour in qualitative studies is transferability, which indicates the extent of applicability of the findings in a similar context (<u>Liamputtong 2013</u>). In this study, purposive sampling and detailed description of the study area may contribute to a better transferability of the study findings. The study context including the study hospitals in Tigray region and the nutritional program in Ethiopia is presented in detail in this thesis which may increase the transferability of the findings. In addition, the use of similar nutritional programs in other regions of Ethiopia and some similarities in social and contextual factors in other settings may increase the transferability of the findings.

Dependability is another parameter used to ensure rigor of qualitative findings and it can be achieved by detailed documentation of the methods used and their justification, data collection procedure and the coherent and consistent relationship established between the methods, data and results (Liamputtong 2013). Dependability in this thesis was maintained by clearly identifying and justifying the methods of data collection, analysis and interpretation employed in a detailed and logical way. In addition, confirmability is also a parameter used to ensure rigor or trustworthiness of a qualitative findings. It indicates that findings of the studies are not from the thoughts of the researcher but "linked to a data" (Liamputtong 2013, p 26). In this study, confirmability of the findings was supported by presenting direct quotes extracted from the interview transcripts and a clear description of the analysis procedures.

Ensuring the accuracy of translation and transcription is vital in improving the rigour of qualitative study findings (Poland 1995). Very few studies note the strategies applied to maintain the quality of translation and transcription. A study conducted by <u>Davidson (2009)</u> indicated the importance of transcribing all accounts of the interview to improve quality and trustworthiness. In this study, the researcher undertook translation (from the local language to English) and transcription simultaneously. A translation and transcription accuracy test was done to improve the transparency and accuracy of translation from the local language to English. Audio records from one adult and one caregiver were selected purposively and a colleague who is conversant in English and Tigrigna (the local language) translated and transcribed from parts of the audio record of one adult and one caregiver. This colleague's translation and transcription was compared with the researcher's translation and transcription. No major difference in the meaning and interpretation of the data was observed but some minor differences in words were noticed which had minimal effect on the interpretation and further analysis of the findings in this study. To address some of the minor differences, the researcher listened back the audio record, used field notes, and his log of events which included participant codes, date, time and location of interview, and surrounding conditions such as weather and events, during data analysis. Thus, such strategies helped to improve the accuracy of translation and transcription of the qualitative data and made an important contribution to the trustworthiness of the findings.

In addition, three transcripts were double coded by the study supervisors to improve transparency of coding processes and this assisted in the interpretation of the themes and sub-themes. The coding on the same transcripts was evaluated and assessed for differences and similarities. Some differences were observed and discussion undertaken to settle these differences in coding for the subsequent interviews. During the analysis process, listening back to the voice recorder when necessary was done to understand the view and expressions of the study participants in their voice and tone.

3.4.4 Data Analysis

Various methods of qualitative data analysis can be applied depending on the purpose of analysis and discipline (Braun and Clarke 2013). Common qualitative data analysis techniques include content, thematic, narrative, discourse and semiotic analysis. Content analysis focuses on the counting and identification of trends and patterns of words or concepts (Liamputtong 2013) but qualitative data analysis in this study goes beyond frequency of words or concepts because the presence of a concept by itself was crucial in the analysis. Similarly, a narrative analysis is a technique used in qualitative data analysis that helps researchers to analyse the chronological lived experiences and their interpretation of participants. During the analysis and presentation of people's experience, crucial elements such as "time, place, plot and scene" are mentioned to assist readers (Liamputtong 2013, p 251). However, the chronological order of people's lived experience is not relevant in this analysis.

Discourse analysis is another method of qualitative data analysis, defined as "an inter-related set of texts and the practices of their production, dissemination and reception that brings an object into being" (Liamputtong 2013, p 253). Discourse analysis mainly focuses on the language and social interactions that exist in the data. However, language and its meaning in the social context was not the purpose of the qualitative research question in this study. Similarly, semiotic analyse which mainly focuses on sign systems and interpretations (Liamputtong 2013) and is used to analysis and interpret image and signs (Jessop 2004). However, signs (images) and their deeper meaning were not the aim of this research question and semiotic analysis was excluded as a method of analysis.

Thematic analysis is one of the most common methods of qualitative data analysis (<u>Liamputtong</u> 2013, p 249). "Thematic analysis is a method for identifying, analysing and reporting patterns (themes) within a data" (<u>Braun and Clarke 2006</u>). The most important difference between thematic analysis and other methods is that thematic analysis does not necessarily relate to a specific theory or model but can be used with pre-existing theories or frameworks (<u>Braun and Clarke 2006</u>; <u>Liamputtong 2013</u>). Thematic analysis allows generation of themes in the absence of meaningful theories and it is applicable in a wide range of "theoretical and epistemological approaches" (<u>Smith and Firth 2011</u>).

A specific form of thematic analysis was used in this study, framework thematic analysis (<u>Smith and Firth 2011</u>). According to <u>Gale et al. (2013, p 2)</u> "the defining feature of the framework analysis is matrix output which shows cases (rows), codes (column) and cells (summarised data)" that can assist the investigator to summarize data. The views of each participant in framework analysis is linked to the framework matrix in the way that maintains the individual's original views. In addition, the framework method uses a clear procedure of data analysis and provides highly structured results (<u>Gale et al. 2013</u>).

There are six steps in framework analysis of qualitative data, transcription, familiarisation with the data, coding, establishing a guiding framework, applying the analytical framework and charting data into the framework matrix (<u>Gale et al. 2013</u>). Thus, framework analysis was selected and found to be suitable for the analysis of the qualitative data in this study for the following reasons.

- 1. Follows clearly defined steps and is easy for novice researchers
- 2. Maintains participants' views and links the original data with the framework matrix and themes.
- 3. Facilitates constant comparison through review of data along the matrix
- 4. Allow iterative coding processes that are easily traceable and facilitate transparency of data analysis.
- 5. Framework qualitative data analysis is not related to specific ontological, epistemological and methodological underpinnings.

In the first step, verbatim translations and transcriptions were made of all audio recorded interviews with adults, caregivers, health providers and program managers. Almost half of the translation and transcription was done during the field work and the remainder afterwards. During the translation and transcription, notes were taken on what was believed to be important for data analysis and interpretation. In addition, a sample of the first two transcripts was sent to supervisors for assessment of adequacy of the transcription and its process was improved based on the feedback.

The second step was reading and re-reading of the transcriptions to gain understanding about the body of data, which is referred to as familiarisation with the interview (Smith and Firth 2011). Having the researcher do both the translation and transcription provided a good opportunity for him to gain familiarisation with the qualitative data. In addition, field notes and notes made during translation and transcription were brought together to create a foundation for further coding and analysis of the qualitative in-depth interviews.

In the third step, four purposively selected transcripts were coded by reading the transcripts line by line. There are two types of coding, selective coding and complete coding. "Selective coding involves identifying a corpus of instances of a phenomenon that you are interested in and then selecting those out" (Braun and Clarke 2013, p 206–207). However, selective coding risks missing the complete meaning of the code and demands prior analytical knowledge. Instead, complete coding of the data related to the research question was chosen. Complete coding "aims to identify anything and everything of interest or relevance to answering your research question within the entire data" (Braun and Clarke 2013, p 206–207). Based on the first four transcripts, 68 codes emerged. In subsequent revision and discussion with supervisors, the 68 codes were collapsed into 13 major themes (parent nodes) with a variable number of sub-themes (child nodes).

In the fourth step, a working analytic framework was developed. Three transcripts were coded and indexed by the researcher and the three supervisors to the major themes and sub-themes. Areas of disagreement were discussed to achieve consensus on the coding framework and process. Finally, a consensus was reached about the coding and indexing framework leading to the development of a codebook. A codebook is a list of all codes generated and relevant to answer the research question and includes definition of each code and some specific examples of texts.

Both the codebook and themes evolved over the process of coding of the interview transcripts. Initially the codes were collapsed to 13 themes and many more sub-themes followed by creating parent and child nodes in NVivo 11 (Welsh 2002) for further indexing of the transcripts and creating new emerging themes. Finally, 8 main themes, 24 themes and about 50 sub-themes emerged from all transcripts.

In the fifth step, charting was done by importing all transcripts into NVivo for further coding and indexing. Charting is the process of "lifting the data from its original context and rearranging it according to the appropriate thematic references" (Bryman and Burgess 2002, p 182). Data coding and indexing was done by reading and re-reading transcripts line by line. Coding and indexing were conducted in a clear and iterative process and ensured that all analysis and interpretations had emerged from the data. Analysis of the qualitative interviews was inductive. All main themes and sub-themes presented in this study emerged from the qualitative data. In addition, to ensure rigorous and systematic analysis, thorough examination of the cross comparisons was made among and across participants and hospitals.

Finally, in the sixth step, a framework matrix was generated which involved the main themes, themes and sub-themes and their description. Interpretation of data and identification of connections between the main themes, themes and sub-themes were undertaken. The data was further interrogated and dissected to identify connections and theorise the concepts.

While data analysis was informed by the socioecological model (<u>Bronfenbrenner 1979</u>), all main themes, themes and sub-themes emerged from the data inductively.

3.5 Reflexivity

"Researcher reflexivity represents a methodological process of learning about self as a researcher, which in turn, illuminates deeper, richer meaning about personal, theoretical, ethical and epistemological aspects of the research question" (Pillow 2010, p 274). An understanding of researcher's role in the process of knowledge generation is important, to account for biases, personal interpretations and experiences and to create a balance between personal understanding and participants' views and to improve the trustworthiness of the findings (Berger 2015; Smith 2006).

The researcher has a strong background in public health and had completed a Master of Public Health prior to starting his PhD research. He had previous research experience in the areas of HIV, community health workers, maternal and child health and nutrition mainly using quantitative approaches in Ethiopia before he started his PhD research, with less qualitative experience.

His skills in quantitative research assisted the process of quantitative data collection, analysis and interpretation. However, he had to develop his qualitative skills over the course of the project. For example, he developed the ability to use probes in the interviews and move his orientation away from quantification towards the use of qualitative techniques and interpretation. Over the course of his PhD study, he was able to balance quantitative and qualitative approaches and applied them in parallel to answer his research question. Generally, the current PhD research has changed his research orientation from purely quantitative to the application of both quantitative and qualitative methods in various ways depending on the need (research question). He has learned various approaches to combine quantitative and qualitative data to answer a research question based on sound methods, methodology and philosophical foundations as described in the methods chapter of this PhD thesis. Based on his experience from the PhD research, he believes that the research question should drive the methodology and methods employed to answer a research question.

He was an academic staff member in Mekelle University, Ethiopia before he started his PhD study, delivering courses such as epidemiology, research methodology, basic and intermediate biostatistics and communicable disease control. He was also responsible for supervision of research projects for undergraduate (Public Health and Medicine) and postgraduate students (Master of Public Health, Master of Public Health Nutrition, Master of Reproductive Health, Master of Biostatistics and Health Informatics). His position as an academic person enhanced adults' and caregivers' willingness to share their detailed experiences, believing their problems with the nutritional program might directly be addressed, despite being told that this research would not have direct impact on their service issues. On the other hand, health providers might focus on the standards or on what should be done instead of the real and existing issues in the nutritional program but he was assuring every participant to provide the exiting issues and experiences so that such information will be a crucial input to improve the nutritional program.

He also undertook research in relevant areas prior to his PhD research which was very helpful for the current study during data collection and interpretation of findings including the use of networks in data collection. Furthermore, his knowledge of the local context and the Ethiopian health system was a crucial input in the interpretation of data. However, having worked in the study area and his particular knowledge of the local context might have limited his holistic view of the problems in the nutritional program. For instance, some issues may not be considered as problems and might be underestimated by him compared with an external researcher who lacked experience about the local context and health system. However, he believes that his supervisors which all are not Ethiopian had helped in addressing this concern and a good balance was achieved.

His knowledge of the local culture and context was important during the field work, data analysis and interpretation. He was born and raised in the study area and can speak, read, write and listen the local language fluently. He also understands the local culture, religion, socioeconomic issues in the study area. This assisted his to gain the full picture during the process of data collection, analysis and interpretation. In addition, knowledge of the local culture has facilitated the qualitative data collection by creating a very good environment between interviewees and the researcher.

As Ethiopia is a patriarchal society, being male and interviewing females may have had some impact during data collection in terms of recruitment and also made participants reluctant to discuss some issues. For example, there is evidence that women feel more comfortable about sharing sensitive issues such as their sexual experience with other women (Berger 2015). HIV is also a sensitive issue among women given all the concerns of stigma related to positive HIV status. However, it was beyond his financial capacity to consider using female interviewers to conduct the in-depth interviews. He attempted to address these gender issues by being friendly, open and non-judgemental. In addition, he has also an awareness of gender normative ways of communicating gender biased stigma around sexually transmitted disease. He has also explained it in detail in sub-section 3.4.2.

3.6 Ethical considerations

During the design and implementation of this study, due emphasis was given to ethical issues in both the quantitative and qualitative studies (**refer to section 3.6.2 and 3.6.3**).

It has also been stated by many that it is important to secure ethical clearance from both the host and funding country or countries (<u>Hyder et al. 2004</u>; <u>Mabunda 2001</u>). Hence, in this study, ethical approval was secured from the funding country (Australia) and host country (the country where this study was conducted) (Ethiopia).

3.6.1 Ethical clearance

Ethical clearance was obtained from Flinders University Social and Behavioural Research Ethics Committee (SBREC) in Australia with reference number 7118 (**Appendix C**) and Mekelle University Ethical Review Committee in Ethiopia (ERC 06211/2016) (**Appendix C**). The ethics approval letters from Flinders University, Australia and Mekelle University, Ethiopia were presented to Tigray Regional Health Bureau (TRHB) to seek support letters from each hospital. Support letters (**Appendix C**) referring to each hospital were secured from TRHB. Overall, there was no unanticipated ethical challenges encountered during the field work in Ethiopia.

3.6.2 Quantitative study

The quantitative study extracted secondary data from a paper-based database in three selected hospitals. To maintain confidentiality of patients' information, data were de-identified during abstraction and collected by people who were experts in hospital health information. To address conflicts of interest, data collectors were informed about the aims of the study and reassured that data collection would not have any influence on their employment matters in the hospital. Neither the researcher nor the supervisors had prior relationships with the data collectors or study participants.

3.6.3 Qualitative study

In studies involving people living with HIV in poor resource settings, there have been some ethical concerns about health providers being involved in the process of recruitment because it can be very difficult for participants to refuse participation due to the fear of service denial (Mabunda 2001). To prevent coercion, health providers' role on the recruitment of adults and caregivers living with HIV was limited to the provision of information about the study and referring them to the researcher in the waiting room for further information or consent. However, health providers did not bring them over to the researcher.

The in-depth interviews were conducted at the HIV clinic of the respective hospitals in a separate and secure room from the main area. Participants were provided with information about the research aims and procedures, informed that there would be no associated financial cost, and assured that it would not affect the service they receive if they did not participate or interrupted the interview at any time. The voluntary basis of the participation was emphasised. Those who agreed to participate were give a consent form to sign and oral consent were taken from those who cannot write and read.

Health providers and program managers were assured that confidentiality of the information provided would be maintained and not used for any purpose than the aims stipulated in the information sheet.

During the interview, culturally and socially acceptable and appropriate words were used. In addition, all interviews were conducted at the convenience of study participants in terms of interview venue, time and date.

Strategies used to prevent coercion included:

- The information sheet emphasised the voluntary basis of participation and that participants'
 decisions would in no way affect access to services, their relationship with the health
 providers or hospitals.
- Study participants were given adequate time to reflect on and discuss with their family members their decision to participate in the study.
- Health providers only provide information about the study and played a limited role in participants' recruitment.
- All participants signed informed consent forms before commencement of the interview and after information had been provided about the aim and voluntary nature of the study.
- Participants were told that they were free to withdraw from the study at any time or refuse to answer any question that made them feel uncomfortable.
- The researcher clearly explained his role as a PhD student and that he had no relationship with the health service or service providers. He wore a name badge from either Flinders or Mekelle University to identify his position as a researcher.
- Potential benefits of participation were not overstated to minimise undue influence/coercion.
 The reimbursement that was offered was not emphasized by LARGE or bold letter relative to other statements.
- It was explained that their participation was exclusively for research purpose and that they may not get direct benefit from participation in the study.

To maintain the confidentiality, translation and transcription was conducted by the researcher and no third party was involved. In addition, information reported in the results chapter of this thesis is de-identified and codes are used to identify quotes.

All participants were compensated AUD 15 after the interview for their time which is a reasonable amount for conducting research in Ethiopia.

The next chapter presents the quantitative results, which include description of the characteristics of the study participants and the determinants of nutritional outcomes in adults and children living with HIV.

CHAPTER 4: QUANTITATIVE RESULTS

Introduction

This chapter presents the findings from the quantitative component of this study in two sections. The first section presents the findings from adults living with HIV enrolled in the nutritional program and is outlined in five sub-sections: 1) demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics; 2) statistical examination of incompleteness versus completeness; 3) statistical examination of non-response versus recovered; 4) statistical examination of relapse versus non-relapse and 5) determinants of frequency of relapse of undernutrition after nutritional recovery.

The second section presents the quantitative findings for children living with HIV in the nutritional program in three sub-sections: 1) demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics; 2) statistical examination of determinants of program incompleteness (default); and 3) statistical examination of determinants of program non-response.

4.1 Adults living with HIV

4.1.1 Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics

Baseline demographic and socioeconomic characterstis

The total number of adult participants or records were 1757. The demographic and socioeconomic characterstics of adults living with HIV enrolled in the nutritional program are presented in **Table 4.1**. The mean age and standard deviation of the study participants was 35.78±9.6 years, with 42.6% of them were between 26 and 35 years. Aproximately, 60% of adults living with HIV in the nutritional program were female and 65% of participants lived in urban areas. About 40% of the study participants were married. In terms of educational characterstics, just over 30% had no formal education and 36% had completed primary education, with fewer than 10% holding a tertiary qualification. Almost half were employed with the remainder unemployed or employed but not working because of ill health (sick leave). Most people lived in households of five or less people, and three quarters of families had children living with them. Over three-quarters reported that they had disclosed their positive HIV status to someone and fewer than 20% of participants belonged to an HIV related community support group.

Table 4.1: Demographic and socioeconomic characteristics of adults living with HIV enrolled in nutritional programs in three hospitals of the Tigray region, Ethiopia, November 2010 to February 2016.

Variables (n=1757)	Categories	Number	Percent
Age in years	<25	216	12.3
	26-35	749	42.6
	36-45	531	30.2
	>46	261	14.9
Sex	Male	649	36.9
	Female	1108	63.1
Residence	Urban	1171	66.6
	Rural	586	33.4
Marital status	Never married	265	15.1
	Married (or de facto)	722	41.1
	Separated	164	9.3
	Divorced	381	21.7
	Widow/Widower	225	12.8
	No education	535	30.4
Education status	Primary	637	36.3
	Secondary	459	26.1
	Tertiary	126	7.2
Religion	Orthodox and other Christian	1659	94.4
	Muslim	98	5.6
Employment	Working	871	49.6
	Employed but not working because of ill health	111	6.5
	Unemployed	732	42.7
House hold family size	≤5	1543	87.8
	>5	207	11.8
Have children	Yes	1346	76.6
	No	411	23.4

Membership of HIV related community support group	Yes	333	19.0
	No	1424	81.0
Disclosure to at least one person	Yes	1366	77.7
	No	391	22.3

Baseline immunological and clinical characteristics of adult HIV patients

The immunological and clinical characterstics of adult participants are presented in **Table 4.2**. Over 80% of the study participants were clinically well and able to work and only 4.4% were bedridden (very severe clinical condition). Similarily, approximately half were in WHO clinical stage I (least severe) and nearly 40% had CD4 counts <200 (worst HIV condition). Almost all study participants were on ART and just over 60% had been on ART for more than 24 months. Over 70% had received cotrimoxazole prophylaxis to prevent opportunistic infections and one-quarter of participants had opportunistic infections. Of these, almost half of them had tuberculosis and other opportunistic infections. Among participants, 45% were anaemic at enrolment to the nutritional program (sign of undernutrition).

Table 4.2: Baseline immunological and clinical characteristics of adults living with HIV enrolled in nutritional programs in three hospitals of the Tigray region, Ethiopia, November 2010 to February 2016.

Variables		Number	Percent
Functional status	Working	1473	83.8
	Ambulatory	207	11.8
	Bedridden*	77	4.4
WHO clinical stage	Stage I	888	50.5
	Stage II	225	12.8
	Stage III	518	29.5
	Stage IV*	126	7.2
Baseline CD4 count	<200	675	39.0
	200–349	488	28.2
	350–500	294	17.0
	>500	274	15.8
Presence of anaemic	Anaemic	687	45.7
	Not anaemic	815	54.3
ART status	Pre-ART	100	5.7
	ART	1657	94.3
Duration on ART	<6 months	324	19.6
	6–12 months	99	6.0
	12-24 months	175	10.6
	>24 months	1059	63.9
Cotrimoxazole prophylaxis	Yes	1297	73.8
	No	460	26.2
Presence of opportunistic infection	Yes	436	24.8
	No	1321	75.2
	ТВ	152	37.3
Type of opportunistic infection	TB and others	47	11.5
	Others	208	51.1

^{*}Stage IV and bedridden shows severe clinical conditions

Nutritional and anthropometric characterstics

Nutritional and anthropometric characteristics of adult participants are shown in **Table 4.3**. Mean BMI with standard deviation at enrolment to the nutritional program was 16.6 ± 1.63. The majority (62.5%) of adults had moderate undernutrition (16≤BMI≤17.99), with 23.1% with severe acute undernutrition (BMI≤16). Approximately three-quarters received three or fewer sachets of the nutritional support per day. Almost all (98.5%) had undergone an appetite test at the commencement of the program with over 65% reporting good appetite. The average duration of stay in the nutritional program was 11.8±4.5 months. Over 90% of participants achieved good weight gain and more than half (55.3%) recovered or graduated from the nutritional program. A further 18.7% did not complete the program and 20% were non-respondents (failed to gain adequate weight). In addition, 2.4% of them were transferred out of the program (to another place or service site before completion) and 2% died while in the nutritional program, but this study was unable to determine whether death was related to undernutrition. Finally, among the adults who graduated from the nutritional program, 17.6% had relapsed at least once.

Table 4.3: Nutritional and anthropometric characteristics of adults living with HIV enrolled in the nutritional program in three hospitals of the Tigray region, Ethiopia, November 2010 to February 2016.

Varia	bles	Number	Percent
Nutritional status at enrolment	Mild acute undernutrition	253	14.4
	Moderate acute under nutrition	1098	62.5
	Severe acute undernutrition	406	23.1
Number of sachets/ days*	≤ 3	1362	77.6
	≥4	394	22.4
Appetite test done	Yes	1731	98.5
	No	26	1.5
Appetite test results	Good*	1150	65.5
	Poor	580	33.0
Subsequent weight gain	Good*	1650	93.9
	Poor	70	4.0
Nutritional outcome	Graduated/recovered	971	55.3
	Non-respondent	379	21.0
	Incomplete (Defaulted)	329	18.7
	Death	35	2.0
	Transferred out	43	2.4
Relapse after nutritional recovery	Yes	170	17.6
	No	798	82.4

^{*} Number sachets changes over enrolment in the nutritional program and what is measured here is the number at the beginning

^{*}Good appetite was shown when the participant finished one sachet in the health facility within 30 minutes.

^{*} Good subsequent weight gain is when the patient's weight continued to improve in two subsequent visits

4.1.2 Incompleteness (default) from the nutritional program and its determinants

The predictors of program incompleteness (default from the nutritional program) were examined using bivariate and multivariate logistic regression. In this analysis, adults who failed to complete the nutritional program were compared with those who had completed the program, regardless of program outcome, to determine potential barriers to program completion. The demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics associated with incompleteness were examined. Statistical significance in bivariate analyses was declared at $p \le 0.3$.

Demographic and socioeconomic characteristics that had statistically significant bivariate associations with nutritional program incompleteness were: gender, place of residence, educational status, marital status, employment, disclosure of HIV status and name of hospital (Table 4.4). Participants who were male and those living in urban areas were more likely not to complete than females and rural residents. In addition, individuals who did not have formal education and those who only attended primary education were more likely not to complete the nutritional program than those who attended secondary education and above. Employed adults were more likely not to complete than their unemployed counterparts. Similarly, adults who had disclosed their positive HIV status were more likely not to complete the nutritional program than those who had not disclosed their positive HIV status to at least one person (Table 4.4).

The immunological and clinical, nutritional and anthropometric characteristics with statistically significant relationships with program incompleteness in the bivariate analysis were baseline WHO clinical stage, functional status, ART status, duration on ART, baseline CD4 count, haemoglobin and nutritional status (**Table 4.4**). Those who were bedridden or ambulatory were less likely to complete the program than those who were able to work or apparently healthy. Participants in WHO clinical stages II, III and IV were less likely to finish the program than those in WHO clinical stage I. Those on pre-ART were less likely to complete the nutritional program than those who were on ART at enrolment and those who were on ART for shorter duration were less likely to complete the nutritional program than those with had been on ART for over 24 months. Those with CD4 counts greater than 500 were more likely to complete the nutritional program than those with lower CD4 counts. In addition, those who were anaemic and with severe undernutrition at enrolment were more likely not to complete than those without anaemia or with mild or moderate undernutrition respectively.

In multivariate analysis, a statistically significant relationship was declared at p < 0.05. In this analysis, the demographic and socioeconomic characteristics that were significantly associated with program incompleteness from the nutritional program were place of residence, employment and name of hospital (**Table 4.4**). Controlling for other variables, urban residents were more likely (1.2 times) not to complete the nutritional program than rural residents. Regarding employment status, those who were employed and working were more likely (1.4 times) not to complete the nutritional program than those who were not employed and not working. However, there was no statistically significant relationship between those who were employed but not working because of ill health compared with those who were not employed. In terms of hospital site, those enrolled in Shul (4.6 times) and Lemlem Karl (2.5 times) hospitals were more likely not to complete than those who attended Mekelle hospital, after controlling for all other variables (**Table 4.4**).

Regarding immunological and clinical, nutritional and anthropometric characterstics, WHO clinical stage, anaemia at baseline and baseline nutritional status were statistically associated with program incompleteness in the multivariate analysis (**Table 4.4**). Those in WHO clinical stages II (2.8 times) and III (1.5 times) were more likely not to complete than those in WHO clinical stage I. In addition, those with anaemia at enrolment were 1.8 times more likely not to complete the nutritional program than those without anaemia. With respect to baseline nutritional status, those who were severely undernourished at baseline were 6.4 times more likely not to complete than those who had mild or moderate undernutrition at enrolment to the nutritional program (**Table 4.4**).

Table 4.4: Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric factors associated with program incompleteness in three hospitals in the Tigray region, Ethiopia, November 2010 to February 2016.

		Nutritional pro	gram completeness			
	Variable	· · · · · · · · · · · · · · · · · · ·			Adimated Odda matic	P
		N <u>o</u> (%)	N <u>o</u> (%)	Crude Odds ratio (95% CI)	Adjusted Odds ratio (95% CI)	
Gender	Male	485(78.9)	130(21.1)	1.12(0.91–1.49)	1.23(0.87-1.70)	0.22
Gerider	Female	865(81.3)	199(18.7)	1.0	1.0	
Residence	Urban	929(82.5)	197(17.5)	1.48(1.15–1.90)	1.44(1.05–1.97) *	0.02
Residence	Rural	421(76.1)	132(23.9)	1.0	1.0	
	Single	210(83.0)	43(17.0)	1.0	1.0	
Maritalanta	Married	554(80.2)	137(19.8)	1.21(0.83–1.76)	1.30(0.80-2.12)	0.29
Marital status	Divorced	414(79.8)	105(20.2)	1.24(0.84–1.83)	1.16(0.69–1.94)	0.58
	Widowed	172(79.6)	44(20.4)	1.25(0.78–2.0)	1.66(0.90–3.05)	0.10
	No education	383(76.8)	116(23.2)	1.56(1.15–2.12)	1.35(0.72–2.53)	0.35
Educational status	Primary education	490(80.3)	120(19.7)	1.26(0.93-1.69)	1.04(0.56-1.92)	0.91
	Secondary education and above	477(83.7)	93(16.3)	1.0	1.0	
Employment status	Working	643(77.4)	188(22.6)	1.52(1.18-1.97)	1.39(1.01–1.93)	0.046

	Employed but not working because of ill health	81(81.8)	18(18.2)	1.16(0.67–2.00)	0.80(0.39-1.65)	0.54
	Not employed and not working	594(83.9)	114(16.1)	1.0	1.0	
Disclosure of HIV	Yes	1037(79.5)	267(20.5)	1.3(0.96–1.76)	1.23(0.83-1.82)	0.295
status	No	313(83.5)	62(16.5)	1.0	1.0	
	Mekelle	907(87.7)	127(12.3)	1.0	1.0	
Name of hospital	Shul	215(62.7)	128(37.3)	4.25(3.19-5.67)	4.6(3.15–6.71) *	0.0001
	Lemlem Karl	228(75.5)	74(24.5)	2.32(1.68–3.20)	2.5(1.69–3.71) *	0.0001
	Working	1167(82.3)	251(17.7)	1.0	1.0	
Functional status	Ambulatory	135(69.2)	60(30.8)	2.07(1.48–2.88)	1.25(0.78–2.0)	0.37
	Bedridden	48(72.7)	18(27.3)	1.74(1.00–3.05)	0.71(0.31–1.67)	0.44
	WHO stage I	743(85.3)	128(14.7)	1.0	1.0	
MILO di indutana	WHO stage II	153(71.8)	60(28.2)	2.28(1.6–3.24)	2.49(1.59–3.91) *	<0.001
WHO clinical stage	WHO stage III	366(76.4)	113(23.6)	1.79(1.35–2.378)	1.46(1.02–2.07) *	0.037
	WHO stage IV	88(75.9)	28(24.1	1.85(1.16–2.94)	1.11(0.60-2.01)	0.75
	<200	469(74.4)	161(25.6)	2.82(1.84-4.30)	1.25(0.73–2.16)	0.41
CD4 sourt	200–349	394(83.5)	78(16.5)	1.63(1.03–2.56)	1.05(0.61–1.81)	0.87
CD4 count	350–500	235(82.7)	49(17.3)	1.71(1.05–2.80)	1.27(0.71–2.3)	0.42
	>500	238(89.1)	29(10.9)	1.0	1.0	

Lla ana a alabin	Anaemic	493(76.0)	156(24.0)	2.05(1.56–2.70)	1.77(1.29–2.41) *	<0.001
Haemoglobin	Haemoglobin Not anaemic		106(13.4)	1.0	1.0	
ART status at	Not on ART	66(70.2)	28(29.8)	1.81(1.14–2.87)	1.42(0.73–1.84)	0.71
enrolment	on ART	1284(81.0)	301(19.0)	1.0	1.0	
	<=6 months	210(70.0)	90(30.0)	2.42(1.79-3.27)	1.61(1.09–2.39)	0.018
Duration on ART at	7–12 months	73(78.5)	20(21.5)	1.55(0.92–2.61)	1.30(0.69–2.46)	0.41
enrolment	13–24 months	126(77.8)	36(22.2)	1.61(1.073–2.43)	1.30(0.79-8.68)	0.31
	>24 months	875(85.0)	155(15.0)	1.0	1.0	
Cotrimoxazole	Yes	971(78.5)	266(21.5)	1.65(1.22-2.22)	0.93(0.6–1.10)	0.76
prophylaxis	No	379(85.7)	63(14.3)	1.0	1.0	
Describes and different	Mild and moderate malnutrition	1159(87.9)	159(12.1)	1.0	1.0	
Baseline nutritional status	Severe malnutrition	191(52.9)	170(47.1)	6.49(4.98-8.46)	6.43(4.69-8.3) *	p<0.001

^{*} *P*<0.05

4.1.3 Non-response to the nutritional program and its determinants

Bivariate logistic regression analyses were performed to identify the predictors of non-response for those that had completed the nutritional program alongside demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics (**Table 4.5**). Statistical significance was again declared at $p \le 0.3$. The demographic and socioeconomic characteristics that were statistically significant were: place of residence, marital status, educational status, employment status, presence of children, disclosure of HIV status and name of hospital. Urban residents were more likely to be non-respondent in the nutritional program than their rural counter parts. In terms of marital status, those who were married, divorced or never married were more likely to be non-respondent than those widowed. Those who had children were more likely to be non-respondent than those who did not and those who had disclosed their positive HIV status were more likely to be non-respondent than those who had not. Looking at the hospitals, those enrolled in Shul and Lemlem Karl hospitals were more likely to be non-respondent than those in Mekelle hospital (**Table 4.5**).

Immunological and clinical, nutritional and anthropometric characteristics in relation to functional status, WHO clinical stage, duration on ART, type of opportunistic infections and baseline nutritional status were found to have statistically significant relationships at $p \le 0.3$. Adults who were ambulatory and bedridden at baseline were more likely to be non-respondent than those who were able to work. In addition, those in WHO clinical stage II-IV were more likely to be non-respondent than those in WHO clinical stage I. Individuals on ART for less than six months were less likely to be non-respondent than those on ART medication for more than 24 months but there was no statically significant relationship between non-response to the nutritional program and staying on ART for 7-12 and 13-24 months. Those who had severe undernutrition at entry to the nutritional program were more likely to be non-respondent than those with mild and moderate undernutrition (**Table 4.5**).

In multivariate logistic regression, all variables found to have statistically significant relationship at $p \le 0.3$ level were examined, and final statistical significance was declared at p < 0.05 (Table 4.5). In this analysis: residence, hospital setting, functional status, WHO clinical stage and nutritional status were found to have statistically significant relationship with non-response to the nutritional program. Adults living with HIV who were urban residents were 1.5 times higher to be non-respondent than rural residents. Individuals enrolled in Shul and Lemlem Karl were 2.9 and 1.5 times more likely to be non-respondent than in Mekelle hospital respectively. In addition, those who were bedridden and in WHO clinical stage IV were more likely to recover than those working and in WHO clinical stage I respectively. Those who had severe undernutrition at enrolment were four times more likely to be non-respondent than those who had mild and moderate undernutrition (Table 4.5).

Table 4.5: Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric factors and non-response in three hospitals in the Tigray region, Ethiopia, November 2010 to February 2016.

	Variables	Nutritio	nal status	Crude OR (95%	Adjusted OR	Р
		Recovered	Non- respondent	CI)	(95%CI)	
		N <u>o</u>	N <u>o</u> (%)			
Sex	Male	349(72.0)	136(28.0)	0.98(0.78–1.28)	1.01(0.75–1.36)	0.94
	Female	622(71.9)	243(28.1)		1.0	
Residence	Urban	315 (74.8)	106(25.2)	1.24(0.94–1.61)	1.46(1.40–2.91) *	0.03
	Rural	656 (70.6)	273 (29.4)	1.0	1.0	
	Never married	153(72.9)	57(27.1)	0.96(0.61–1.51)	1.91(0.53–1.57)	0.94
Marital status	Married	412(74.4)	142(25.6)	0.89(0.61–1.31)	0.87(0.57–1.31)	0.42
Divorced	Divorced	282(68.1)	132(31.9)	1.21(0.82–1.79)	1.15(0.75–1.77)	0.68
	Widowed/widower	124(72.1)	48(27.9)	1.0	1.0	
Educational status	No education	272(71.0)	111(29.0)	0.98 (0.55–1.15)	1.11(0.79–1.58)	0.54

Primary	348 (71.0)	142(29.0)	1.0 (0.75–1.34)	1.06(0.77–1.45)	0.73
Secondary and above	351(73.6)	89(28.1)	1.0	1.0	
Unemployed	446 (75.1)	148(24.9)	0.76(0.60-0.97)	0.96(0.71–1.21)	0.73
Employed	54(66.7)	27(33.3)	1.0	1.0	
No	230(71.4)	92(28.6)	1.0	1.0	
Yes	741 (72.1)	287(27.9)	1.32(0.99–1.77)	0.87(0.61–1.23)	0.36
No	229(73.2)	84(26.8)	1.0	1.0	
Yes	742(71.6)	295(28.4)	1.08(0.82–1.44)	1.21(0.87–1.67)	0.26
Mekelle	695(76.6%)	212(23.4)	1.0	1.0	
Shul	119(55.3)	96(44.7)	2.65(1.94–3.61)	2.92(2.04–4.19) *	<0.0001
Lemlem Karl	157(68.9)	71(31.1)	1.48(1.08–2.04)	1.49(1.05–2.11) *	<0.047
Working	849 (72.8)	318(21.2)	1.0	1.0	
Ambulatory	88(65.2)	47(34.8)	1.43(0.98–2.08)	1.09(0.71–1.670)	0.57
Bed ridden	34(70.8)	14(29.2)	1.10(0.58–2.08)	0.36(0.15–0.83) *	0.02
	Secondary and above Unemployed Employed No Yes No Yes Mekelle Shul Lemlem Karl Working Ambulatory	Secondary and above 351(73.6) Unemployed 446 (75.1) Employed 54(66.7) No 230(71.4) Yes 741 (72.1) No 229(73.2) Yes 742(71.6) Mekelle 695(76.6%) Shul 119(55.3) Lemlem Karl 157(68.9) Working 849 (72.8) Ambulatory 88(65.2)	Secondary and above 351(73.6) 89(28.1) Unemployed 446 (75.1) 148(24.9) Employed 54(66.7) 27(33.3) No 230(71.4) 92(28.6) Yes 741 (72.1) 287(27.9) No 229(73.2) 84(26.8) Yes 742(71.6) 295(28.4) Mekelle 695(76.6%) 212(23.4) Shul 119(55.3) 96(44.7) Lemlem Karl 157(68.9) 71(31.1) Working 849 (72.8) 318(21.2) Ambulatory 88(65.2) 47(34.8)	Secondary and above 351(73.6) 89(28.1) 1.0 Unemployed 446 (75.1) 148(24.9) 0.76(0.60-0.97) Employed 54(66.7) 27(33.3) 1.0 No 230(71.4) 92(28.6) 1.0 Yes 741 (72.1) 287(27.9) 1.32(0.99-1.77) No 229(73.2) 84(26.8) 1.0 Yes 742(71.6) 295(28.4) 1.08(0.82-1.44) Mekelle 695(76.6%) 212(23.4) 1.0 Shul 119(55.3) 96(44.7) 2.65(1.94-3.61) Lemlem Karl 157(68.9) 71(31.1) 1.48(1.08-2.04) Working 849 (72.8) 318(21.2) 1.0 Ambulatory 88(65.2) 47(34.8) 1.43(0.98-2.08)	Secondary and above 351(73.6) 89(28.1) 1.0 1.0 Unemployed 446 (75.1) 148(24.9) 0.76(0.60-0.97) 0.96(0.71-1.21) Employed 54(66.7) 27(33.3) 1.0 1.0 No 230(71.4) 92(28.6) 1.0 1.0 Yes 741 (72.1) 287(27.9) 1.32(0.99-1.77) 0.87(0.61-1.23) No 229(73.2) 84(26.8) 1.0 1.0 Yes 742(71.6) 295(28.4) 1.08(0.82-1.44) 1.21(0.87-1.67) Mekelle 695(76.6%) 212(23.4) 1.0 1.0 Shul 119(55.3) 96(44.7) 2.65(1.94-3.61) 2.92(2.04-4.19) * Lemlem Karl 157(68.9) 71(31.1) 1.48(1.08-2.04) 1.49(1.05-2.11) * Working 849 (72.8) 318(21.2) 1.0 1.0 Ambulatory 88(65.2) 47(34.8) 1.43(0.98-2.08) 1.09(0.71-1.670)

WHO clinical stage	Stage I	552(74.3)	191(25.7)	1.0	1.0	
	Stage II	108(70.6)	45(29.4)	1.20(0.82–1.77)	1.02(0.65–1.60)	0.56
	Stage III	245(66.9)	121(33.1)	1.43(1.09–1.88)	1.03(0.74–1.44)	0.37
	Stage IV	66(75.0)	22(25.0)	0.96(0.58–1.60)	0.52(0.28–0.98) *	0.047
Duration on ART	>24 months	624(71.3)	251(28.7)	1.0	1.0	
	13–24 months	92(73.0)	34(27.0)	0.92(0.60-1.40)	0.85(0.54–1.37)	0.39
	6–12 months	57(78.1)	16(21.9)	0.7(0.39–1.24)	0.66(0.35–1.24)	0.18
	<6 months	152 (72.4)	58(27.6)	0.95(0.68–1.33)	0.85(0.58–1.26)	0.47
Nutritional status at baseline	Mild and moderate malnutrition	885(76.4)	274(23.6)	1.0	1.0	
	Severe malnutrition	86(45.0)	105(55.0)	3.94(2.88–5.41)	4.25(3.02–5.98) *	<0.0001

^{*} Significant at P<0.05

4.1.4 Relapse of undernutrition and its determinants

After recovery from undernutrition, adults living with HIV were followed for a mean time of 68.5 months, (95% CI, 67.0–69.9) and the cohort contributed to 131,153-person months of follow up in the nutritional program. Bivariate and multivariate Cox regression analyses were conducted to examine the predictors of relapse after nutritional recovery n=170 (17.6%).

In bivariate Cox-regression analysis, statistical significance was declared at $p \le 0.3$ (Table 4.6). Educational status, employment, membership of an HIV community support group, duration on ART and presence of opportunistic infection were found to be statistically associated with relapse. Those who attended primary and secondary education were at greater risk of relapse than those who attended tertiary education, with no difference for those without formal education. Looking at employment, those who were unemployed were at greater risk of relapse than employed individuals. Those who were not members of HIV community support groups had a higher risk of relapse than those who were members. In addition, those had been on ART for more than 24 months were twice as likely to relapse as those who had been on ART for less than six months. Finally, adults who had an opportunistic infection at baseline were at greater risk of relapsing than those with no opportunistic infection (Table 4.6).

In the final model, multivariate Cox regression analysis was used to determine the independent predictors of relapse of undernutrition after nutritional recovery. Accordingly, educational status, membership of HIV community support group, duration on ART and presence of opportunistic infections were found to be statistically significant for relapse of undernutrition. Those who attended primary and secondary education were 3.7 and 3.3 times more likely to relapse than those who attended tertiary and above, with no difference for those who did not attend formal education. Adults who were not members of an HIV community support group were at 1.7 times greater risk of relapsing into undernutrition than those who were members of HIV support group. Moreover, those who had been on ART for more than 24 months were at greater risk of relapsing than those who had been on ART for less than six months. Finally, adults living with HIV who had an opportunistic infection at enrolment to the nutritional program were 1.7 times more likely to relapse than those who had not (Table 4.6).

Table 4.6: Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric factors and relapse of undernutrition after nutritional recovery in the Tigray region, Ethiopia, November 2010 to February 2016.

Variables		Relapse malnutrition	of	Crude Hazard ratio (95% CI)	Adjusted Hazard ratio (95% CI)	P
		No	Yes	(3376 61)	(3378 31)	
		N <u>o</u> (%)	N <u>o</u> (%)			
Sex	Male	289(83.5)	57(16.5)	0.92(0.67–1.27)	0.91(0.64–1.29)	0.59
	Female	509(81.8)	113(18.2)	1.0	1.0	
Residence	Urban	533(81.5)	121(18.5)	1.16(0.83–1.62)	0.94(0.65–1.34)	0.74
	Rural	265(84.4)	49(15.6)	1.0	1.0	
Marital status	Single	131(86.8)	21(13.2)	1.0	1.0	
	Married	342(83.2)	69(16.8)	1.33(0.81–2.19)	1.27(0.76–2.13)	0.36
	Divorced	228(80.9)	54(19.1)	1.49(0.89–2.49)	1.50(0.88–2.56)	0.13
	Widowed	97(78.2)	27(21.8)	1.57(0.88–2.82)	1.36(0.74–3.43)	0.33
Educational status	No education	231(84.9)	41(15.1)	1.055(0.75–1.49)	2.84 (0.87–9.26)	0.08
	Primary	276(79.8)	70(20.2)	1.48(1.07–2.03)	3.68(1.15–11.77) *	0.03

	Secondary	276(79.8)	70(20.2)	1.39(1.0–1.93)	3.25(1.01–10.48) *	0.049
	Tertiary	291(83.1)	59(16.9)	1.0	1.0	
Employment	Working	425(84.7)	77(15.30	1.0	1.00	
	Not working	353(79.3)	92(20.7)	1.36(1.00–1.84)	1.32(0.97–1.81)	0.08
Membership of community support	Yes	127(73.0)	47(27.0)	1.0	1.0	
Зарроге	No	671(84.50)	123(15.5)	1.87(1.33–2.63)	1.78(1.25–2.54) *	0.001
Functional status	Working	694(81.9)	153(18.1)		1.0	
	Ambulatory and bedridden	104(86.0)	17(14.0)	0.76(0.46–1.26)	5.2(1.63–16.67)	0.005
Duration on ART	≤6 months	133(88.1)	18(11.9)	1.0	1.0	
	6–12 months	52(91.2)	5(8.8)	0.70(0.26–1.89)	0.83(0.3–2.25)	0.71
	13–24 months	80(87.0)	12(13.0)	1.0(0.48–2.07)	1.28(0.61–2.70)	0.52
	>24 months	495(79.6)	127(20.4)	1.78(1.08–2.91)	2.15(1.27–3.63) *	0.004
Opportunistic infection	Yes	182(77.8)	52(22.2)	1.38(1.0–1.91)	1.68(1.18–2.39) *	0.004
	No	616(83.9)	118(16.1)	1.0	1.0	

	Mild	186(80.9)	44(19.1)	1.0	1.0	
Baseline nutritional status						
	Moderate	543(83.3)	109(16.7)	0.85(0.60–1.21)	0.93(0.65–1.33)	0.08
	Severe	68(80.2)	17(17.8)	1.09(0.62-1.90)	1.34(0.62–2.08)	0.3

^{*} *P*<0.05

4.1.5 Frequency of relapse of undernutrition and its determinants

Data to examine the frequency of relapse of undernutrition after nutritional recovery was only accessible for the period between September 2012 and July 2016. As indicated in **sub-section 4.1.4**, 170 (17.6%) relapsed after nutritional recovery, with 124 (72.9%) relapsing once and 31(18.2%) relapsing twice. The remaining 10 (5.9%) and 5 (2.9%) participants relapsed three or four times after nutritional recovery respectively **(Table 4.7)**.

Unadjusted associations between demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characterstics with frequency of relapse (relapsed once versus relapsed two or more times) were examined and statistically significant relationships were considered at p < 0.3. Demographic and socioeconomic characterstics that were found to be statistically significant at $p \le 0.3$ were place of residence, marital status, educational status, employment and disclosure of HIV status. Adults living with HIV from rural areas were more likely to relapse more than once than urban residents. Similarily, while single individuals were less likely to relapse more than once, married and divorced adults were more likely to relapse more than once than widowed individuals. Concerning educational status, those with no education or attended up to primary school were more likely to relapse more than once than those who attended secondary and above. In addition, individuals who had disclosed their positive HIV status were more likely to relapse more than once than those who had not (Table 4.7).

Immunological and clincial, nutritional and anthropometric characteristics with statistically significant relationships at $p \le 0.3$ were functional status, WHO clinical stage, duration on ART, haemoglobin level, contrimoxazole prophylais and baseline nutritional status. Adults living with HIV who were ambulatory or bedriden at baseline were more likely to relapse more than once than those who were able to work. Similarly, those in WHO clinical stages III and IV were more likely to relapse more than once than those in WHO clinical stages I and II. Individuals who had been on ART for less than six months were more likely to relapse more than once than those who had been on ART for more than six months. Furthermore, those who were moderately and severely undernourished were more likely to relapse more than once than those with mild undernutrition at enrolment (Table 4.7).

After adjusting for different demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics, place of residence, education, employment status, functional status, heamoglobin level, and baseline nutritional status were statistically significantly associated with relapse more than once at *p*<0.05. Rural residents were three times more likely to relapse more than once than urban residents. Similarly, those who did not have formal education were four times more likely to relapse more than once than those who attended secondary and above, but there was no difference between those who had attended primary and secondary education and above. Concerning employment status, those who were employed were more likely to relapse more than once than those who were unemployed. Looking at the clinical characteristics, individuals who were bedridden were five times more likely to relapse more than once than those who were anaemic at enrolment were nine times more likely to relapse more than once than those who were not. Examining the baseline nutritional status of participants, those who were severely or moderately undernourished were four and nine times more likely to relapse more than once than once than those who had mild undernutrition (**Table 4.7**).

Table 4.7: Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics and relapse of undernutrition more than once, in three hospitals in the Tigray region, Northern Ethiopia, November 2010 to February 2016.

Variables		Relapsed only	Relapsed more	COR (95% CI)	AOR (95%CI)	P
		once	than once			
		No (%)	No (%)			
Place of residence	Urban	95(78.5)	26(21.5)	1.0	1.0	
	Rural	29(59.2)	20(40.8)	2.52(1.23–5.16)	3.14(1.30–7.57)*	0.011
Marital status	Single	17(85.0)	3(15.0)	0.6(0.13–2.72)	0.49(0.076–3.19)	0.46
	Married	46(65.7)	24(34.3)	1.74(0.62–4.91)	1.50(0.40–5.62)	0.55
	Divorced	41(75.9)	13(24.1)	1.06(0.35–3.19)	0.6(0.15–2.35)	0.46
	Widowed	20(76.9)	6(23.1)	1.0	1.0	
Educational status	No education	25(61.0)	16(39.0)	5.65(1.98–16.19)	3.88(1.22–12.36)*	0.022
	Primary	46(65.7)	24(34.3)	4.61(1.73–12.25)	2.23(0.75–6.58)	0.15
	Secondary and above	53(89.8)	6(10.2)	1.0	1.0	
Employment status	Working	42(53.8)	36(46.2)	7.81(3.44–17.73)	3.86(1.15–12.94)*	0.029
	Not working	82(90.1)	9(9.9)	1.0	1.0	
Disclosure of HIV status	Yes	94(69.6)	41(30.40	2.62(0.95–7.22)	2.44(0.79–7.53)	0.12

	No	30(85.7)	5(14.3)	1.0	1.0	
Functional status	Working	117(76.5)	36(23.0)	1.0	1.0	
T differential states	Ambulatory or bedridden	7(41.2)	10(58.8)	4.64(1.65–13.08)	5.21(1.63–16.67)*	0.005
WHO clinical stage	Stage I and II	89(78.1)	25(21.9)	1.0	1.0	
·····o cimical calgo	Stage III and V	35(62,5)	21(37.5)	2.14(1.06–4.30)	1.26(0.45–3.55)	0.67
Duration on ART	<=6 months	9(50.0)	9(50.00	3.38(1.24–9.17)	2.51(0.79–8.00)	0.121
	> 6 months	111(77.1)	33(22.9)	1.0	1.0	
Haemoglobin level	Anaemic	30(51.7)	28(48.3)	5.54(2.61–11.74)	9.28(3.39–25.33) *	0.0001
	Not anaemic	89(85.6)	15(14.4)	1.0	1.0	
Cotrimoxazole	Yes	81(69.2)	36(30.8)	1.91(0.86–4.22)	1.86(0.69–5.04))	0.22
	No	43(81.1)	10(18.9)	1.0	1.0	
Baseline nutritional	Mild malnutrition	39(88.6)	5(11.4)	1.0	1.0	
status	Moderate malnutrition	75(68.8)	34(31.2)	3.54(1.28–9.76)	4.30(1.37–13.54)) *	0.013
	Severe malnutrition	10(58.8)	7(41.2)	5.46(1.43–20.88)	9.90(2.04–48.14) *	0.004

^{*}P<0.05

4.2 Children living with HIV

4.2.1 Demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics

Baseline demographic and socioeconomic characteristics

Table 4.8. Mean age with standard deviation was 8.2 ±3.8 years, 102 (43.2%) of them were between 5 and 10 years of age and 52.5% were male. In terms of residence, 75.8% of children were from urban areas and 82.6% of children lived with their parents. The remaining children lived with guardians, grandparents, siblings and in orphanages. Nearly half of the parents of children were living together. The majority of children's mothers (84.1%) and fathers (72.3%) were alive at enrolment. While smaller numbers of mothers were employed (37.4%), most fathers were employed (71.4%). The children's birth order ranged from first to fourth and above. Almost three-quarters of children were attending school, with not yet reaching school age being the main reason for not attending school. Most children (80.1%) were attending Mekelle hospital.

Table 4.8: Baseline demographic and socioeconomic characteristics of children with HIV enrolled in nutritional program in the Tigray region, Ethiopia, November 2010 to February 2016.

Variables		N <u>o</u>	Percent
Age	< 5 years	62	26.3
	5–10 years	102	43.2
	>10 years	72	30.5
Sex	Male	124	52.5
	Female	112	47.5
Residence	Urban	179	75.8
	Rural	57	24.2
Child lives with	Parents	195	82.6
	Gurdian	15	6.4
	Grand parents	2	0.8
	In orphanage	14	5.9
	Sibilings	10	4.2
Marital status of parents, n=195	Mother and father live together	100	51.3
	Divorced	16	8.2
	Widowed	5	2.7
	Single parent father	18	9.2
	Single parent mother	54	27.7
Mother alive, n=208	Yes	175	84.1
	No	33	15.9
Emploment status of mother if alive. n=147	Employed	55	37.4
	Unemployed	92	62.6
Father alive, n=202	Yes	146	72.3
	No	56	27.7
Employment status of father if alive.n=126	Employed	90	71.4
	Unemployed	36	28.6
Child's birth order	First	32	13.6
	Second	42	17.8
	Third	32	13.6
	Fourth and above	28	11.9
Child atted school	Yes	170	72.0
	No	66	28.0
Reason for not atteding school, n=66	Too young	60	90.1
	Lack of funds	6	9.1
Name of hospitla	Mekelle	189	80.1
	Lemlem Karl	24	10.2
	Shul hospital	23	9.7

Baseline immunological and clinical characteristics

Baseline immunological and clinical characteristics of children living with HIV are presented in **Table 4.9**. Over half were in WHO clinical stage I and more than 85% of children were on ART during or before enrolment in the nutritional program, with 72% on ART for more than 24 months. Similarly, the majority (88.6%) of study participants were taking cotrimoxazole prophylaxis and 22.0% had an opportunistic infection. Among those with opportunistic infections, 27% had TB, followed by TB plus other infections.

Table 4.9: Immunological and clinical characteristics of children with HIV enrolled in the nutritional program in the Tigray region, November 2010 to February 2016.

Variables		N <u>o</u>	Percent
	Stage I	132	55.9
WHO clinical stage	Stage II	42	17.8
	Stage III	50	21.2
	Stage IV	12	5.1
ART status at enrolment	On pre-ART	29	12.3
	On ART	207	87.7
Duration on ART	<12 months	27	13.0
	13-24 months	31	15.0
	>24 months	149	72.0
Contrimoxzole propylaxis	Yes	209	88.6
	No	27	11.1
Presence of opportunistic infection	Yes	52	22.0
	No	184	78.0
Type of opportunistic infection	ТВ	14	26.9
	TB and other	10	19.2
	Other	28	53.8
Eligibility criteria for ART	WHO clinical stage only	28	11.9
	CD4 or TLC only	15	58.5
	CD4% only	47	19.9
	WHO and CD4% only	5	2.1
	Not eligible	18	7.6

Nutritional and anthropometric characteristics

The nutritional characteristics of children living with HIV are described in **Table 4.10**. Almost 80% of children had moderate acute undernourishment at enrolment, and the remaining 12.3% and 8.1% had mild and severe acute undernourishment respectively. Over 80% had been in the nutritional program for three months, with 6.4% for more than three months and 11.9% for less than three months. Over 70% of children had recovered (graduated) from the nutritional program, with 14.0% non-respondent and 14% failing to complete the nutritional program. Two children died and one was transferred out (moved to other service area) from the nutritional program. Finally, among the children living with HIV, 7.2% relapsed after nutritional recovery.

Table 4.10: Nutritional and anthropometric characteristics of children with HIV enrolled in the nutritional program in the Tigray region, Ethiopia, November 2010 to February 2016.

Variables		N <u>o</u>	Percent
Nutritional status at enrolment	Mild acute undernutrition	29	12.3
	Moderate acute undernutrition	188	79.7
	Severe acute undernutrition	19	8.1
Duration on nutritional program	<3 months	28	11.9
	3 months	193	81.8
	>3 months	15	6.4
Nutritional outcome	Graduated	167	70.8
	Non-respondent	33	14.0
	Defaulted	33	13.9
	Died	2	0.8
	Transferred out	1	0.4
Relapse of malnutrition	Yes	12	7.2
	No	154	92.8

4.2.2 Program incompleteness

The demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics of children associated with program incompleteness were examined. In the bivariate analysis, statistical significance was declared at p < 0.3. Age, place of residence, mother's employment and child's schooling status were identified to be statistically significant demographic and socioeconomic characteristics associated with program incompleteness. Children aged under 5 years were most likely to complete the program. Urban residents were more likely to complete the nutritional program than their rural counterparts. Children with employed mothers were less likely to complete the nutritional program than those whose mothers were not employed. In addition, children attending school were less likely to complete the nutritional program than those not attending (Table 4.11).

In bivariate analysis, clinical stage, ART status at baseline and baseline nutritional status were found to have statistically significant associations with program incompleteness. Children living with HIV in WHO clinical stage II were more likely to complete than those in WHO clinical stage I, while those in WHO clinical stages III and IV were more likely not to complete the nutritional program than those in WHO clinical stage I. Children on pre-ART before or at enrolment to the nutritional program were more likely to complete the nutritional program than those on ART. Concerning baseline nutritional status, children enrolled with moderate or severe acute undernutrition were more likely not to complete the nutritional program than those with mild undernutrition at enrolment.

In multivariate analysis to identify the independent predictors of program incompleteness, statistical significance was declared at p < 0.05. No demographic and socioeconomic characteristics were statistically significant and so were removed from the multivariate logistic regression model. While no clinical characteristics were found to be statistically significant, undernutrition status at enrolment was significantly associated with program incompleteness. Children with severe acute undernutrition at enrolment to the nutritional program were nearly fourteen times more likely not to complete the nutritional program than those with mild acute undernutrition at enrolment to the nutritional program.

Table 4.11: Bivariate and multivariate logistic regression to identify the predictors of program incompleteness in the Tigray region, Ethiopia, November 2010 to February 2016.

Variables		Program completness		AOR(95% CI)	P
	Completed	Not completed			
	N <u>o</u> (%)	N <u>o</u> (%)			
<5	55(88.7)	7(11.3)	1.0	1.0	
5–10	85(83.3)	17(16.7)	1.57(0.61–4.04)	1.85(0.56–6.08)	0.35
>10	60(83.3)	12(16.7)	1.57(0.57–4.28)	1.41(0.37–5.36)	0.58
Urban	155(86.6)	24(13.4)	1.72(0.8–3.71)	1.93(0.75–4.98)	0.17
Rural	45(78.9)	12(21.1)	1.0	1.0	
Employed	51(78.5)	24(21.5)	1.6(0.68–3.75)	1.4(0.57–3.47)	0.3
Not employed	70(85.4)	12(14.6)	1.0	1.0	
Yes	140(82.4)	30(17.6)	2.14(0.85–5.42)	0.82(0.2–3.39)	0.67
No	60(90.9)	6(9.1)	1.0	1.0	
Stage I	111(84.1)	21(15.9)	1.0	1.0	
Stage II	38(90.5)	4(9.5)	0.56(0.18–1.72)	0.42(0.9–2.04)	0.29
	5–10 >10 Urban Rural Employed Not employed Yes No Stage I	Completed No(%) <5	Completed Not completed No(%) No(%) <5	Completed Not completed Ng(%) Ng(%) 5-10 85(83.3) 17(16.7) 1.57(0.61-4.04) >10 60(83.3) 12(16.7) 1.57(0.57-4.28) Urban 155(86.6) 24(13.4) 1.72(0.8-3.71) Rural 45(78.9) 12(21.1) 1.0 Employed 51(78.5) 24(21.5) 1.6(0.68-3.75) Not employed 70(85.4) 12(14.6) 1.0 Yes 140(82.4) 30(17.6) 2.14(0.85-5.42) No 60(90.9) 6(9.1) 1.0 Stage I 111(84.1) 21(15.9) 1.0	Completed Not completed Ng(%) Ng(%) 55 55(88.7) 7(11.3) 1.0 1.85(0.56-6.08) >10 85(83.3) 17(16.7) 1.57(0.61-4.04) 1.85(0.56-6.08) >10 60(83.3) 12(16.7) 1.57(0.57-4.28) 1.41(0.37-5.36) Urban 155(86.6) 24(13.4) 1.72(0.8-3.71) 1.93(0.75-4.98) Rural 45(78.9) 12(21.1) 1.0 1.0 Employed 51(78.5) 24(21.5) 1.6(0.68-3.75) 1.4(0.57-3.47) Not employed 70(85.4) 12(14.6) 1.0 1.0 Yes 140(82.4) 30(17.6) 2.14(0.85-5.42) 0.82(0.2-3.39) No 60(90.9) 6(9.1) 1.0 1.0 Stage I 111(84.1) 21(15.9) 1.0 1.0

	Stage III and IV	51(82.3)	11(17.7)	1.14(0.52–2.54)	0.79(0.27–2.30)	0.61
ART status at enrolment	Pre-ART	22(75.9)	7(24.1)	1.0	1.0	
	On ART	178(86.0)	29(14.0)	0.51(0.20–1.31)	1.04(0.25–4.42)	0.96
Baseline nutritional status	Mild malnutrition	27(93.7)	2(6.9)	1.0	1.0	
	Moderate malnutrition	163(86.7)	25(13.3)	2.07(0.46–9.25)	2.00(0.24–16.39)	0.52
	Severe malnutrition	10(52.6)	9(47.4)	12.2(2.23–66.2)	13.71(1.41–133.85)*	0.024*

^{*}P<0.05

4.2.3 Non-response to the nutritional program

In this section, demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics associated with non-response for children who completed the program were examined and identified in bivariate and multivariate analysis. Statistical significance in the bivariate analyses was considered at p < 0.3. Demographic and socioeconomic characteristics that had statistically significant associations with non-response in bivariate analysis were age, place of residence, with whom the child lived, employment status of child's mother and father, and child's schooling. Children aged between five and ten years and those older than ten were more likely to be non-respondent than those aged under five years of age. Children living with HIV from rural areas were more likely to be non-respondent than their urban counterparts. Children living with HIV who lived with their parents were more likely to be non-respondent than those who lived with others (guardians, orphanage, siblings and grandparents). In addition, those children whose mothers or fathers were employed were more likely to be non-respondent than those whose parents were not employed. Children attending school were more likely to be non-respondent to the nutritional program than those who were not (Table 4.12).

The immunological and clinical, nutritional and anthropometric characteristics that were found to have a statistically significant relationship with program non-response in bivariate analysis were WHO clinical stage, ART status at enrolment, presence of opportunistic infection at enrolment and baseline nutritional status. Children living with HIV in stages II, III and IV were more likely to be non-respondent to the nutritional program than those in stage I. Moreover, being on pre-ART was associated with non-response compared with those on ART. Presence of an opportunistic infection before enrolment was also associated with non-response. Furthermore, children with moderate or severe acute undernutrition at enrolment were more likely to be non-respondent than those with mild acute undernutrition (Table 4.12).

In multivariate logistic regression analysis to identify the independent predictors of non-response to the nutritional program, statistical significance was considered at p<0.05. Only a small number of demographic and socioeconomic, immunological and clinical characteristics were found to have statistically significant associations with program non-response. Maternal and paternal employment were associated with non-response. Children with their mothers or fathers employed were six times more likely to be non-respondent to the nutritional program than those whose mothers or fathers did not work. Similarly, children with an opportunistic infection at enrolment were more likely to have an unsuccessful nutritional outcome in the nutritional program than those with no opportunistic infection (**Table 4.12**).

Table 4.12: Bivariate and multivariate logistic regression to identify the predictors of program incompleteness in the Tigray region, Ethiopia, November 2010 to February 2016.

Variables		Program response status		AOR (95% CI)	P
	Recovered	Non-respondent			
	N <u>o</u> (%)	N <u>o</u> (%)			
<5	48(87.3)	7(12.7)	1.0	1.0	
5–10	72(84.7)	13(15.3)	1.24(0.46–3.33)	1.85(0.56–6.08)	0.31
>10	47(78.3)	13(21.7)	1.90(0.70–5.17)	3.56(0.72–17.64)	0.62
Urban	155(86.6)	24(13.4)	1.0	1.0	
Rural	45(78.9)	12(21.1)	1.37(0.58–3.19)	1.95 (0.0.75–4.98)	0.17
Employed	36(70.6)	15(29.4)	2.82(1.12–7.11)	6.17(1.08–35.04)*	0.045
Not employed	61(87.1)	9(12.9)	1.0	1.0	
Employed	55(70.5)	23(29.5)	2.09(0.64–6.79)	6.70(1.08–41.64)*	0.048
Not employed	20(83.3)	4(16.7)	1.0	1.0	
Yes	140(82.4)	30(17.6)	2.14(0.85–5.42)	0.82 (0.2 –3.39)	0.79
No	60(90.9)	6(9.1)	1.0	1.0	
	5–10 >10 Urban Rural Employed Not employed Employed Not employed Yes	Recovered No(%) <5	Recovered Non-respondent No(%) No(%) 48(87.3) 7(12.7) 5-10 72(84.7) 13(15.3) >10 47(78.3) 13(21.7) Urban 155(86.6) 24(13.4) Rural 45(78.9) 12(21.1) Employed 36(70.6) 15(29.4) Not employed 61(87.1) 9(12.9) Employed 55(70.5) 23(29.5) Not employed 20(83.3) 4(16.7) Yes 140(82.4) 30(17.6)	Recovered Non-respondent No(%) No(%) 5-10 72(84.7) 13(15.3) 1.24(0.46-3.33) >10 47(78.3) 13(21.7) 1.90(0.70-5.17) Urban 155(86.6) 24(13.4) 1.0 Rural 45(78.9) 12(21.1) 1.37(0.58-3.19) Employed 36(70.6) 15(29.4) 2.82(1.12-7.11) Not employed 61(87.1) 9(12.9) 1.0 Employed 55(70.5) 23(29.5) 2.09(0.64-6.79) Not employed 20(83.3) 4(16.7) 1.0 Yes 140(82.4) 30(17.6) 2.14(0.85-5.42)	Recovered Non-respondent No(%) No(%)

WHO stage	Stage I	94(84.7)	17(15.3)	1.0	1.0	
	Stage II	32(84.2)	6(15.8)	1.04(0.38–2.86)	0.42(0.09–2.09)	0.28
	Stages III and IV	41(80.4)	10(19.6)	1.35(0.57–3.20)	0.75(0.25–2.22)	0.60
ART status at enrolment	Pre-ART	15(68.2)	7(31.8)	2.73(1.04–7.33)	2.14(0.34–13.47)	0.78
	On ART	152(85.4)	26(14.6)	1.0	1.0	
Presence of opportunistic infection	Yes	27(67.5)	13(32.5)	3.34(1.50–7.58)	8.18(2.20–30.41)*	0.006
	No	140(87.5)	20(12.5)	1.0	1.0	
	Mild malnutrition	24(88.9)	3(11.1)	1.0	1.0	
Baseline nutritional status	Moderate malnutrition	138(84.7)	25(15.3)	1.45(0.41–5.18)	0.09(0.003–3.04)	0.37
	Severe malnutrition	5(50.0)	5(50.0)	8.00(1.45–44.92)	0.10(0.006–1.87)	0.81

^{*}P <0.05

4.3 Results summary

4.3.1 Adults living with HIV

Overall, 55.3% of adults living with HIV were estimated to have recovered (graduated) from undernutrition in the nutritional program. However, 21.0% of adults were non-respondent after completion of the three-to-six month period that is the recommended duration of the program, while the remaining 18.7% failed to complete the program. Approximately 2.0% of adults living with HIV died while they were in the nutritional program and 2.4% were transferred out.

In terms of demographic and socioeconomic characteristics that predicted outcomes from the nutritional program, gender was not significant in any multivariate analysis. Urban residence predicted failure to complete the program and non-response from the nutritional program but did not predict relapse of undernutrition after nutritional recovery. Those enrolled at the Shul and Lemlem Karl hospitals were consistently more likely not to complete or to become non-respondent from the nutritional program than those enrolled in Mekelle hospital. Educational status at baseline was not statistically associated with non-response, but was associated with relapse of undernutrition after nutritional recovery, whereby those who had attended primary and secondary education were more likely to relapse compared with those who attended tertiary and above. Those who were employed at enrolment to the nutritional program were more likely not to complete than those who were not employed, but there was no difference in actual program outcomes or relapse after recovery.

WHO clinical stage had a statistically significant relationship with both program incompleteness and non-response. Those in WHO clinical stages I, II and IV were more likely not to complete the nutritional program than those in WHO clinical stage I. However, the relationship between non-response and WHO clinical stage was an inverse one, whereby participants in WHO clinical stage IV were more likely to recover than those in WHO clinical stage I. On the other hand, adults living with HIV who had bedridden functional status were less likely to be non-respondent than those who were able to work or were apparently healthy, but there was no statistically significant difference with nutritional program incompleteness. Concerning relapse, neither WHO clinical stage nor functional status had statistically significant associations with relapse of undernutrition after nutritional recovery. Finally, baseline nutritional status predicted program incompleteness, non-response and relapse of undernutrition after nutritional recovery consistently. In all cases, adults living with HIV with severe acute undernutrition at the beginning were more likely to fail to complete, be non-respondent and relapse than those with mild and moderate acute undernutrition.

4.3.2 Children living with HIV

Nearly 71% of children living with HIV enrolled in the nutritional program recovered (graduated) from the nutritional program while 14% each failing to complete or were non-respondent. A small number (7.2%) of children living with HIV relapsed after nutritional recovery in the program. No demographic and socioeconomic, immunological and clinical characteristics at enrolment were found to be statistically significant determinants of nutritional program incompleteness. Some demographic and socioeconomic characteristics such as maternal and paternal employment were found to be associated with program non-response. In addition, presence of opportunistic infection at enrolment was related to program non-response. While severe acute undernutrition at enrolment was significantly associated with program incompleteness, there was no significant relationship with nutritional program non-response. Predictors of relapse were not determined because of the small sample size.

In the next chapter, the findings of the qualitative component of the study are presented to help explain the quantitative results and further explore the barriers to and facilitators of utilisation of nutritional programs in HIV care settings.

CHAPTER 5: QUALITATIVE RESULTS

Introduction

The previous chapter examined the individual level determinants of nutritional outcomes for adults and children living with HIV who were enrolled in the nutritional program. This chapter presents the findings of the qualitative study. The chapter starts with a description of study participants including sociodemographic characteristics and their personal/family histories of persons living with HIV. The chapter then presents key themes and sub-themes that emerged from individual interviews in relation to factors that enabled or constrained the utilisation of the nutritional program amongst study participants. Indicative quotes from participants are presented to illustrate identified themes and sub-themes. The chapter concludes with a summary of the qualitative study findings.

5.1 Description of study participants

5.1.1 Demographic and socioeconomic characteristics

In total, 48 in-depth interviews were conducted with purposively selected participants from three study hospitals. As shown in **Table 5.1** participants included 20 adults living with HIV⁶, 15 caregivers of children living with HIV⁷, 11 health providers with more than one year of work experience in the nutritional program, and two program managers. Among those interviewed, there was one adult female and one caregiver who lived with HIV but also worked as ART adherence and nutritional counsellors (peer educators) and they were counted only as adults and caregivers. The health providers who participated in the interviews were from different professions such as nurses, public health officers and practitioners involved in the treatment, care and support of patients living with HIV.

⁶ Referred to as adults.

⁷ Referred to as caregivers.

The age of adult participants ranged from 20 to 52 years, while the caregivers ranged from 27 to 48 years. Twelve (60%) adult participants and all caregivers were females. The majority of participants (60% and 73.3% of adults and caregivers respectively) lived in urban areas. Concerning the educational status, 'no education' was reported by four adults (20%) and five caregivers (33.3%). Half of adult participants (n=10) and almost one third of caregivers (n=5) had completed primary education. Furthermore, six (30%) adults and six (33.3%) caregivers had completed secondary education. All health providers held Bachelor of Science degrees and above. Among study participants, six (30%) adults were single, with six (30%) adults and nine (60%) caregivers married at the time of the interview. The remaining 40% of adults were widowed or divorced. The income of adults ranged from 'no reliable and regular source of income' to approximately 6000 Ethiopian Birr (equivalent to AUD \$458) per month while that of the caregivers ranged from no reliable income to 4000 Ethiopian Birr (equivalent to AU\$243) per month which is much less than the average per capital income of AUD \$857 in Ethiopia. (Table 5.1).

Table 5.1: Characteristics of interview participants, Tigray region Ethiopia.

Variables		Participants		
		Adults,	Caregivers,	Program
		n=20	n=15	staff, n=13
Mean age	Mean age	37.2±9.7	36±7.3	35.3± 8
	Mekelle	8	6	5
Hospital	Lemlem Karl	6	5	3
	Shul	6	4	3
	TRHB	N/A*	N/A	2
	Male	8	0	6
Gender	Female	12	15	7
Residence	Urban	12	11	13
	Rural	8	4	0
Educational	No education	4	5	0
level	Primary	10	5	0
	Secondary	6	5	0
	BSc and above	0	0	13
Marital	Single (never	6	1	2
status	married)			
	Married	6	9	9
	Widowed	5	3	0
	Divorced	3	2	1

^{*}Not applicable

Most adult participants were interviewed during their second visit to the nutritional program, while others were on their third visit or had graduated. Three adults graduated in the third month and two graduated after the third month. Similarly, seven (46.7%) children had graduated. Three children graduated in the third month and four after the third month (fourth, fifth or later).

5.1.2 HIV disease and family history of adults living with HIV

Study participants were asked about the history of their HIV condition, the duration of the disease and its diagnosis. In 75% of cases, the diagnosis of HIV was confirmed through an HIV screening test at health facilities when attending for other health conditions, or during antenatal care or labour/delivery for women. The remaining participants were diagnosed through self-initiated HIV testing and counselling. The duration of positive HIV status ranged from eight months to 15 years at the time of the interviews and while the main mode of HIV transmission was through heterosexual contact, 15% of adult participants reported acquiring HIV infection in childhood via mother to child transmission.

All adults were currently on ART. Time on ART ranged from three months to 14 years, with 60% of adults were on ART for more than six years and only a small number (n=3) for less than a year. Most adults started ART treatment immediately after HIV diagnosis but four delayed ART for as long as three years after being diagnosed with HIV because of their refusal to seek care.

At the time of interview, about half (n=9) of adult participants reported a history of previous enrolment in the nutritional program before their current enrolment.

The majority of adult participants (60%) had no other family members living with HIV or AIDS while the remainder had a family member, such as partner or children living with HIV. Two female adult participants were not aware of the HIV status of their partners because of the partners' refusal to undertake HIV screening. Opportunistic infections such as tuberculosis and diarrhoea were reported by three adults living with HIV at the time of interview and all were seeking care for the specified condition.

5.1.3 HIV disease and family history of children living with HIV and their caregivers

With one exception, all caregivers interviewed were the biological mothers of the children under study and the main mode of HIV transmission in children was through mother to child transmission. Eleven caregivers reported that their children were aware of their positive HIV status. The remaining four children were not aware of their positive HIV status because of their perceived young age and caregivers' fears about the child's reaction to the HIV diagnosis.

Caregivers reported that all children were currently on ART. The time since confirmation of child's positive HIV status ranged between 3 and 11 years. Diagnosis of HIV was mainly made during antenatal care, labour or during a health facility visit for other illnesses. Five children started ART immediately after confirmation of positive HIV status while three caregivers delayed this for up to three years because of their perception that ART or other care services had no benefits for their child. Instead these caregivers preferred to visit traditional healers or use holy water as a treatment. In addition, caregivers, particularly those who were the biological mothers of the children, attended HIV care for ART treatment and other HIV services including the nutritional program for themselves for the same or longer length of time as the target child.

Three children and their caregivers had been previously enrolled in the nutritional program. In all three hospitals under study, Saturdays were allocated for follow-up visits for children living with HIV. This provided them with an opportunity to communicate and play with each other. Two caregivers reported that their children had opportunistic infections such as tuberculosis and diarrhoeal disease during enrolment in the nutritional program and were being treated for these conditions at the time of interview. Eight of the HIV positive children had HIV negative siblings while one had an HIV positive sibling. The family HIV status of children living with HIV is summarised in **Table 5.3**.

Table 5.2: Summary of children and their family HIV status.

Family member HIV status	Number
HIV negative siblings	8
HIV positive siblings	1
Children with no siblings	6
Children with both parents HIV positive	5
Children with one parent HIV positive	13

5.2 Emerging barriers and facilitators

Six main themes emerged from the analysis of the interviews with adults, caregivers, health providers and program managers:

- 1. Understanding about weight loss
- 2. Motivation for participation in the nutritional program
- 3. Experience of the nutritional program
- 4. Broader health system factors
- 5. Sociocultural factors
- 6. Nutritional outcomes

5.3 Understanding about weight loss

Weight loss is the main criterion for a patient's enrolment in the nutritional program. Weight loss in people living with HIV may happen because of multiple factors related to the illness and its treatment, but also because of other reasons. An understanding of patients' perceptions of weight loss is vital to understand the challenges in utilising the nutritional program. In the interviews, adults and caregivers related weight loss to food/dietary issues and non-dietary related factors.

Not eating well as a result of lack of energy or appetite was the main dietary factor reported by participants.

The reason for my weight loss is because I can't eat well. Because of decrease of my energy I can't eat well, and I also tell them [the health providers] that I am not eating well (Adult male, age 32–21). 8

Actually, I was not good at eating from the very beginning and my appetite was not good even before my illness (Adult female, age 29_3).

Others related it to a lack of access to adequate food:

Inability to take adequate food.... We are not food self-sufficient and able to support ourselves in our home. Therefore, I can't provide him [her son] with necessary things (Caregiver, age 30_3).

In addition, some caregivers perceived that the weight loss of their children was due to poor child feeding practices such as poor breastfeeding practice, and inadequate complementary feeding since infancy. A caregiver stated:

To me additional food for children starts at six months. So, the child becomes malnourished because I didn't follow his dietary practice properly from that time at the beginning that I was unable to provide him with the necessary food (Caregiver, age 30_3).

A range of non-dietary factors were also perceived as contributing to weight loss. These included: ART medication, HIV illness and other opportunistic illness, alcohol and smoking addiction, stress and labour intensive work.

⁸ _2: indicates the serial number of the respective participants which ranges 1–20 for adults, 1–15 for caregivers, 1-11 for health providers and 1-2 for program managers.

There were contrasting views about ART treatment as a reason for weight loss. Late HIV diagnosis and ART initiation were perceived by some participants as a reason for weight loss. Some adults and caregivers suggested that delay in starting ART or inappropriate intake of ART may cause weight loss while others believed ART itself can be the main reason for weight loss. In addition, some participants believed that poor scheduling (not taking ART medication at the same time every day) could be the cause of weight loss.

I don't have a clock to take my ART medication and I usually miss my time to take the ART medication. So, I take my ART medication anytime. This could be the reason for my weight loss [Adult female, age 36 19].

Other key reasons for weight loss shared by many study participants were related to factors such as stress and worry about matters including stigma and discrimination, presence of an HIV positive child or family member, and economic problems such as housing and basic amenities. For example, an adult female stated:

Most of us (HIV patients) live in rented houses which also contributes to stress, stigma and discrimination. This results in loss of weight and thinness (Adult female, age 30_4).

Another male HIV patient added that:

I am not sure, but it could be because of stress and the disease condition by itself that contributes to weight loss [Adult male, age 29 8].

5.4 Motivation to participate in the nutritional program

Participants were asked the reasons for initial enrolment and continued utilisation of the nutrition program.

Participants reported a range of reasons. These included weight loss and lack of appetite, recommendations from health providers and the government, and the lack of sufficient food in the household. A few participants were unable to provide any reason for their enrolment in the nutritional program.

Weight loss was the most commonly cited motive to participate in the program. For some, this was the sole reason and for others motivation to enrol was also accompanied by a concern about their lack of appetite:

Because my weight has decreased and to improve my weight, health condition and to increase my weight. There is imbalance between my weight and age. They identified my problem and approved my enrolment into the program (Adult female, age 31 1).

In addition, participants believed that the nutritional support (Plumpynut) would improve their weight and overall health status:

It is the Plumpynut⁹ that benefits the child very well. Because it is a very balanced food. I believe that consuming this food is more beneficial than others (Caregiver, age 30_3).

Some cited recommendations from health providers and government as the main reason for their enrolment in the nutritional program:

It [the nutritional support] is given and prepared by doctors to treat us. So, it is important and beneficial for us as it contains some important contents (Adult female, age 39 11).

Other participants, especially those who lived in urban areas and had an unreliable source of income or who were unemployed, noted the lack of sufficient food in the household as a reason for their enrolment in the program. These views were stated by both adults and caregivers in all three hospitals and both male and female participants, particularly those who were divorced or widowed. These participants reported occasions when they were running short of food and thus not able to eat adequately.

If you have something to eat, it should be fine but if you don't have anything to eat like me this food support is very important (Adult male, age 40_18).

A few participants were not able to offer any reason for their enrolment in the program.

I don't know, they prescribe me, and I take it (the nutritional support). They told me that it is an additional food and it is good (Adult female, age 48_9).

The overall understanding of the program by adults and caregivers was limited to the nutritional support (Plumpynut/sup) rather than other elements of the program such as nutritional counselling and mechanisms to sustain nutritional wellbeing. Two different perspectives existed in this regard. For some interviewees, particularly those who reported service provider's recommendation as their main motivation to enrol in the program, the nutritional support was considered as an important medicine to treat undernutrition.

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⁹Plumpynut/Plumpysup in the quotes refers the nutritional support used in the nutritional program.

The second view considered the nutritional support as a privilege for having positive HIV status or reward for ART adherence. A small number of participants (two adults and one caregiver) felt that they had been denied the nutritional support because they had not lost weight. It appeared that these individuals understood the eligibility criteria for enrolment in the program but resisted acceptance of it and demanded the nutritional support. For example, the female caregiver participant quoted below seemed to be annoyed at not being diagnosed with weight loss because she saw weight loss as an avenue to get financial and material support and the nutritional support itself.

To my child, they weighed him and gave him supplementary food but me, they weighed me and didn't give me anything. Because they said, my weight and height are good. But they should give the food for everybody equally. Plumpynut is only given to those with low weight. (Caregiver, age 27–1).

The same participant further stressed the need to distribute the nutritional support and other benefits equally rather than according to weight:

...when some benefits come, they don't distribute it fairly. Everybody here who is using medications doesn't have enough of everything. They don't see everyone equally. They always say that your weight is high or something else to deny you from any benefit. (Caregiver, age 27_1).

Some health providers were concerned about potential dependence on the supports given at the health facility including the nutritional support:

Some patients become very reliant on the supports (soaps, water treatment jerrycan and the nutritional support) given from the health facility because they believe they should get supported due to their HIV condition (Health provider_2).

The findings revealed that the motivation to enter the program partly results from issues beyond individual nutritional status, in particular poor livelihood and poverty, which also affected program utilisation. The broader influences of poor livelihood and poverty will be discussed later in the socio-cultural theme in the forthcoming section.

Adults and caregivers were asked to discuss what helped them to remain in the nutritional program. The key reasons were: 1) a belief that the Plumpynut has higher nutritional value than other foods; 2) concerns about weight and improvement in weight and associated impacts on health and wellbeing; and 3) positive experiences in the health service. These are discussed in more detail below.

5.4.1 The nutritional support perceived as better than other foods

Many adults and caregivers believed that the nutritional support (Plumpynut and Plumpysup) had a higher nutritional value for their HIV condition than other homemade foods. An adult participant noted:

It [the nutritional support] is all balanced food. So, it is very different from local foods. The contents are different from what I eat every day at home. It has more benefits than any food that is consumed at home. So, this is small in size when compared with local foods, but it is important. (Adult female, age 39 11).

A female caregiver also echoed this belief by saying:

The Plumpynut is a balanced food and includes different ingredients. But the food prepared at home is not as balanced as the Plumpynut. The homemade food may contain one or two ingredients but the Plumpynut has many ingredients (Caregiver, age 28-6).

Some people believed that the high salt content of the Plumpynut would encourage them to drink more water than home-made foods. For some, it was believed that increasing water intake would dilute the ART and other medications and minimise their side effects:

It is very good to take water because, it helps to dilute the Bactrim and ART medication. When you eat the Plumpynut, it helps you to drink more water and decreases gastric upset (Adult female, age 29 3).

It has medicinal value and it also helps you to drink more water. It [the nutritional support] benefits your kidney and your gut. In general, it benefits everything to your body. I never used to drink more water because when I take the medication, I drink little water but after I start using the Plumpynut, I start drinking a lot of water (Adult female, age 45_2).

5.4.2 Concern about weight loss and health in the nutritional program

Adults and caregivers carefully monitored their weight and associated worsening of HIV with a decline in health status more generally. For example, an adult female stated:

When I come here for my regular follow up, I primarily see my weight during my weight measurement to check any change in my weight and overall health condition (Adult female, age 31_1).

A positive experience of improved overall health including increased appetite and weight contributed to ongoing utilisation of the program:

It gives you strength at first. If you eat the Plumpynut, your energy will be fine. After I use the Plumpynut, my strength is good (Adult female, age 36_19).

I think, I take the Plumpynut for my weight to increase and my health to improve. It also gives you good energy and is good with the ART medication (Adult female, age 20 10).

Some participants, mainly those who lived in urban areas and attended Mekelle hospital, had a comprehensive understanding of the nutritional program beyond the nutritional support. According to this group, improved weight, appetite and health were ascribed to continuous use of the nutritional program and application of the nutritional counselling, follow up and monitoring.

.... they measure my weight and found that my weight was very low and I was diagnosed with malnutrition. After that I was given the Plumpynut to take it four sachets per day. I consumed it four sachets per day according to their recommendation. First, I eat my own food at home and following, I take the Plumpynut. ...it is good for my weight and overall health improvement (Adult female, age 45 2).

5.4.3 Positive experiences with the health service

Because of their chronic HIV condition, adults and caregivers had strong links with the health service for their HIV care and with other social support services. Utilisation of services including the nutritional program was highly influenced by their experiences of previous contact with the health service. Adults and caregivers with positive experiences were highly motivated to continue their engagement with the nutritional program. Participants cited good relationships with health providers, trust in HIV services, and the comprehensive and free HIV care services. These views were particularly prominent in relation to Mekelle and Shul hospitals.

The way they handle you is very good and excellent. Especially there is one health provider who is always good to me. I also didn't hide anything from her. I tell her everything... (Adult male, age 40_18).

An adult male added another experience with another health provider:

.... everything that I am getting here [in the health services] is giving me life that I am able to work and support myself (Adult male, age 34_13).

These participants were all adults living with HIV and attending Mekelle or Shul hospitals. Mekelle hospital was the biggest hospital in terms of staffing, catchment and number of people living with HIV attending the HIV clinic. It was also nearest to the regional health headquarters where the health service is organised. Shul and Lemlemkarl hospitals were in similar settings, each located about the same distance from the regional health headquarters in Mekelle.

In addition, participants felt that health providers in the HIV care service provided a respectful range of care. A health provider from Shul hospital was seen as particularly supportive, kind and respectful. This provider not only addressed immediate medical needs of participants but also assisted with other social and economic issues that may have affected utilisation of nutritional care and other HIV services. Participants reported examples of advocacy and support, like advice about sending children to school, starting small businesses and assisting participants with their marital problems.

Next to God are our health providers who give us everything. So, we have to follow their advice strictly. Because I am getting better and better now. Because I benefited a lot from their counselling, I usually follow and apply what the health providers told me (adult female age 27_15).

However, some (3 adults and 2 caregivers) expressed concerns that they were not always involved in decisions about their care, such as organisation of appointment dates and prescribing of nutritional support without further clarification. When health providers set appointment dates without consultation, patients and caregivers may miss key appointments if the dates are not suitable for them.

5.5 Experience of the nutritional program

Patients' experience of the different elements of the nutritional program including nutritional counselling, health service, the nutritional support (Plumpynut food) and their prior experience in the program had an impact on their current program utilisation.

5.5.1 Adherence to the nutritional program

Issues around adherence to the nutritional program that emerged from the interviews included appointment times, ration size and applicability of nutritional counselling. From the viewpoint of health providers, missed appointments and not consuming the prescribed amount in a day were key non-adherence challenges to the program. This was particularly an issue for patients on pre-ART. People on ART were seen as more committed to the HIV care process for ART medication and treatment of other illnesses compared with those in pre-ART who only visited health facilities once every six months for CD4 monitoring.

Similarly, adults addicted to alcohol and other drugs were found to be less adherent to the nutritional program:

Clients who consume alcohol, don't come to their appointment date and skip their appointment date five to six days, the outcome is not good. That is my observation (Health provider 4).

Non-adherence to the nutritional program was higher in adults than children partly because of the selling of nutritional support, fasting, stigma and discrimination which will be discussed in the following sections.

5.5.2 Experience of the nutritional support

Interviews explored the experiences of adults and caregivers with the nutritional support. This includes issues around preparation of the nutritional support and its consumption and method of use, ration size, taste, side effects, selling and sharing practices and attitudes around the use of nutritional support and stigma.

Preparation, consumption and taste of the nutritional support

The nutritional program used two types of nutritional supports, Plumpynut for severely undernourished people and Plumpysup for those moderately undernourished. The taste of Plumpynut was reported as acceptable by most participants despite its sugary and oily tastes, while Plumpysup tasted salty and oily and was not liked by many adults. Some participants said they could distinguish between the two types of nutritional support by their taste. There were also variations in the taste, with some batches of Plumpysup described as saltier than others and difficult to consume.

The Plumpynut that I took at the beginning was so nice but the one I took recently was too salty and it is very difficult to consume it. sometimes I couldn't eat two sachets per day. (Adult female, age 25_17).

According to health providers, complaints and defaults from the program related to the taste of the nutritional support were more common in adults than in children, and concerns with Plumpysup were more pronounced than with Plumpynut and affected patients' utilisation of the nutritional program.

Program guidelines recommend that people consume the nutritional support directly from the sachet without mixing it with other foods or drinks, and similar advice was provided by health providers, but participants frequently reported mixing the nutritional support (Plumpynut/Plumpysup) with water, milk or other foods. Various preparation methods were reported, such as consuming it directly from the sachet, spreading Plumpynut over bread, or mixing it with other foods or drinks such as milk, eggs, yogurt and vegetables. A number of participants prepared soup by mixing the nutritional support with water or milk. The main reasons for mixing Plumpynut was to improve the taste, increase consumption and to extend its period of use so as to minimize visits to collect it, avoid boredom with it and reduce side effects.

I mix it with water to minimize the salty taste of the Plumpynut (Adult male, age 34_13).

I mix it with milk to easily swallow it. If you eat it alone, it causes gastritis (Adult female, age 45 2).

Two health providers encouraged the practice of mixing the nutritional support with drinks or food to address poor appetite and improve consumption of it.

When they tell us this [mixing], if it is beneficial, we encourage them to keep doing [mixing] it (Health provider_10).

Almost all adults and caregivers believed that the nutritional support did not need cooking but some were cooking it by mixing with various foods.

Yes, I also use it in the form of porridge by cooking but I eat it with bread for most of the time (Adult female, age 44_9).

Ration size of the nutritional support

The nutritional program recommends ration size based on the severity of undernutrition measured by BMI and MUAC in adults and weight-for-height and MUAC in children. Accordingly, adults with severe acute undernutrition are recommended to take up to four sachets per day while those with mild and moderate undernutrition are recommended to take up to two sachets per day.

The ration size used by most participants ranged between 30 and 120 sachets of Plumpynut/Plumpysup per month, or one to four sachets per day depending on the severity of undernutrition. Some reported using about 30 sachets per month, equivalent to one sachet per day. There was a general sense among participants that the current ration size (based on body weight) was adequate to regain their weight. One caregiver noted:

Yes, it was enough. Previously he was taking three per day. It is given based on your weight. Based on that they may give you one, two or three. They gave him two per day now because his weight is alright (Caregiver, age 30_3).

However, a few adult participants commented on the importance of increasing the ration size for quicker weight gain.

One thing that I am thinking is, two per day should be increased from two to three or four per day and the minimum discharging time should be four months (Adult male, age 52_5).

Selling practice and attitude towards the nutritional support

Health providers indicated the selling of the nutritional support as one of the main \challenge in the program. According to health providers, those who sold their nutritional support took longer to recover from undernutrition because of default or ended as non-responders to the nutritional program. None of the interview participants reported selling their nutritional support during their current enrolment and all were aware of the negative consequences on their weight and overall health status if they did so.

It [selling of the nutritional support] would have negative consequences to me. Because I was given to replace my weight loss and if I sell it I may not improve my weight. You may also get sicker and sicker which will result in further illness (Adult female, age 20_10).

However, participants were aware of other patients living with HIV who sold their nutritional support. They also witnessed the availability of the nutritional support in local shops that suggested selling by participants (the nutritional support should not normally be available in the market). However, there was no evidence to indicate that the availability of nutritional support in the market was due to health providers or other parts of the supply chain selling it. One reason for selling the nutritional support reported by participants was addiction to alcohol and smoking.

They use it at the beginning well but after they know it well, they sell it to buy cigarettes and other things. They use it for some time properly at the beginning and show good progress but then start selling it and relapse again (Adult male, age 48–11).

The reason people are selling the Plumpynut for about four or five birr is that it is to fulfil some short time needs such as alcohol and other addictions (Adult male, age 54 7).

A health provider and program manager argued that people sell the nutritional support because of their economic condition to purchase other household consumables such as oil or coffee beans:

Instead of eating it for himself only, they want to sell and change it for other household needs such as sugar, salt or oil. Most of the time the reason is this but the base is the poor livelihood condition. So, they are not doing it intentionally but it is because of their problems (Health provider_9).

Even though the patients were counselled well, one reason for selling could be the existing economic problems. Poverty by itself would encourage individuals to sell it and spend the money on something that matters to the family is there (Program manager 1).

This issue was also pointed out by a caregiver from her previous enrolment in the nutritional program:

There are many things a child needs to eat but usually it is difficult to get them. So what people usually do is they sell the Plumpynut to change it to pasta and other foods because they don't have money for pasta and other foods. During my previous enrolment I was selling half of it (the Plumpynut) to buy other foods for my child (Caregiver, age 30–3).

Another caregiver believed that people sell and exchange the nutritional support with other food items to prevent the disclosure of their positive HIV status and the associated stigma (discussed further below).

... selling is there because people are afraid of being identified as HIV patients and stigma. They are afraid of being seen with the box (Caregiver, age 41_14).

Furthermore, boredom with the nutritional support was another reason for selling the nutritional support:

There was one person who lived next to me taking the Plumpynut every time, but he was selling it all in rural areas as well in the towns because he was fed up eating the Plumpynut. One day, I found him selling the Plumpynut, but I told him that he shouldn't sell it (Caregiver, age 41_14).

Sharing practices and attitudes towards nutritional support

While some adults said that they did not share the nutritional support with anyone, the majority (65%) of participants reported experiences of sharing the nutritional support with their children and other family members. For adults, it was difficult to consume the nutritional support in front of their children and other family members while they needed more food. Some caregivers also pointed out that other children (rather than the index child) wished to share the nutritional support and this was difficult to avoid:

... His brothers especially his elder one insists that we give him the Plumpynut and so we give it to him. If I say to the older HIV negative child that it is a food given to his brother from a hospital to improve his health, he still insists that I give it to give him and I usually give him one per day (Caregiver, age 30_2).

Sometimes if his brother insists, he gave him some, as well his sisters shares with him. All of his brothers and sister share the Plumpynut with him. So, he usually gives them one sachet per day (Caregiver, age 45 11).

In particular, sharing the nutritional support among family members assisted in keeping the HIV condition hidden from children who were not informed of their positive HIV status.

Health providers also reported on sharing practices, particularly in the case of children living with HIV:

In children, the big problem is sharing it [nutritional support] at home. When there is a malnourished child in a home, then when he takes Plumpynut/sup, his brothers and sisters may share with him. So, sharing is a big problem in children as most children like the taste (Health provider_10).

Sharing in adults was also reported by health providers to be more common in mothers, as indicated in the quote below:

Yes, there is sharing among household members. As far as there is an economic problem, it is not necessarily selling but also sharing. Because if it is given to him, it is likely that the mother will share it with his siblings. If given two sachets then the mother gives one to her other child and keeps one for the HIV positive child (Health provider 7).

Even though adults and caregivers were against sharing of the nutritional support, sharing was inevitable and occurred on a frequent basis because of lack of understanding of the implications of sharing, lack of family consideration of the nutritional program, food sharing culture and norms and food insecurity and poverty. Issues of food insecurity in relation to the nutritional program are addressed in the following theme.

Side effects of the nutritional support

Adults and caregivers testified that there were side effects attributed to the use of nutritional support. These included discomfort, stomach upsets and gastritis, nausea and vomiting, diarrhoea in adults and vomiting in children. Health providers argued that side effects were attributed to the sugary, salty and oily content of the nutritional support. Side effects, combined with taste, were reasons for the high number of defaults from the program.

The other problems associated with this [the nutritional support] are also related to complaints such as gastric upset, sugary and salty taste (Health provider_3).

I use it by mixing with water to prevent my stomach upset. (Adult male, age 34_13).

Side effects from the nutritional support generally occurred during the early months of enrolment in the nutritional program and subsided in later months.

I was started on Plumpynut and I stopped the Plumpynut because I was not comfortable with it at beginning but my weight start dropping below 40 (Adult female, age 29_3).

At the beginning, I was feeling some nausea when taking the Plumpynut but I am comfortable to take it now (Adult female, age 48_9).

Contribution of the nutritional support to stigma

Adults and caregivers believed that consumption of Plumpynut contributed to HIV stigma and discrimination. In most circumstances, the community related the nutritional support to HIV illness. This made it difficult for people living with HIV to use the nutritional support in the sight of their friends, neighbours and even families, particularly in situations where the positive HIV status was not disclosed. The mechanisms and circumstances under which the nutritional program more broadly contributed to stigma are discussed in the next main theme under the sociocultural factors. Concerns around stigma and discrimination leading to the refusal of nutritional support were highlighted by health providers:

...I have encountered a woman with this problem [stigma and discrimination] who is unable to take the Plumpynut because of fear of being seen by others (Health provider_2).

5.5.3 Experience of nutritional counselling

In addition to the provision of nutritional support, nutritional counselling was another element of the program. Study participants were asked about their experiences of and attitudes towards the content and acceptability of the nutritional counselling. Barriers to implementing counselling advice and its applicability in their daily living were also explored. There were various views about the nutritional counselling. For example, some adults from Shul and Lemlem Karl hospitals stated that no counselling or information about the nutritional program was provided during their enrolment in the program. Other adults and caregivers noted that nutritional counselling was solely limited to the use of the nutritional support.

Timing and duration of the nutritional counselling

In general, participants had limited knowledge about the frequency and duration of counselling sessions, with the majority indicating nutritional counselling as a one-off event after enrolment.

...At the beginning when they give you [the nutritional support], they [the health providers] tell you that it is a medication: that is all, nothing else after... (Adult male, age 54_7).

As described by study participants, nutritional counselling was not provided on an ongoing basis for the duration of enrolment in the nutritional program.

The things that need improvement is that when they give you the Plumpynut, they should provide you with adequate information about how and when to use it. For example, as I told you, I don't have much information for how long I will use it and when to use it, when I would be discharged (Adult male, age 29 8).

Two providers, from Shul and Mekelle hospitals, mentioned: "the nutritional counselling was given at every visit despite shorter duration" because of patient overload. Generally, while the program guidelines specified ongoing counselling, in practice the frequency and content appeared to vary between the different hospitals.

Content of the nutritional counselling

While the content of nutritional counselling varied – seven general nutrition information components were meant to be covered as follows (<u>Fedral HIV Prevention and Control Office of Ethiopia, USAID</u> and Food and Nutrition Technical Assistance (FANTA) 2008):

- 1. See a health worker for periodic nutrition assessment (especially weight).
- 2. Eat more and different kinds of foods.
- 3. Maintain a high level of hygiene and sanitation.
- 4. Drink plenty of clean, safe (boiled or treated) water.
- 5. Maintain a healthy lifestyle.
- 6. Seek early treatment for infections and manage symptoms through diet.
- 7. Take medicines as advised by your health worker and manage food and drug interactions and side effects.

However, participants reported that in practice the nutritional counselling mainly focused on the nutritional support (Plumpynut/sup), with limited coverage of dietary practice and personal hygiene.

There were two views expressed by adults and caregivers about understanding the purpose of the nutritional counselling. The first and most common one was about the proper use of the nutritional support (Plumpynut/Plumpysup), to get the next ration, as illustrated in the quote below:

The nutritional counselling has helped me to understand the benefits of the nutritional support (Plumpynut/sup) (Adult male, age 50_6).

... counselling is very important. It helps me to understand its [the nutritional support] benefits to him [the child]) and use it properly, on time and get the necessary next ration (Caregiver, age 27_1).

The second view among a minority of participants considered a more comprehensive approach to counselling that improved overall health and included proper use of the nutritional support, balanced consumption of food, drinking clean water and seeking care for any sickness.

..., it [the counselling] benefited me to get well. The health providers advised us to eat balanced food, to drink clean water and seek care for any sickness (Adult female, age 30_4).

Generally, the nutritional counselling mainly covered counselling about the nutritional support.

However, a small number of adults and caregivers reported receiving no nutritional counselling at all and being sent home only with the nutritional support:

Maybe since I am coming from far away, I may not reach the teaching session. Otherwise, I have not yet come across any counselling or teaching session (Adult female, age 37_16).

A small number of adults said they did not understand the reason for stopping the nutritional program after completion because inadequate information was given about the criteria to graduate.

Actually, they teach us properly, but they didn't tell me anything about why I am stopping it (Adult female, age 39 11).

In contrast, health providers stated that counselling about the benefits, duration and methods of use were addressed in detail during the counselling sessions. For example, one said:

For those enrolled in the food by prescription, we counsel them in detail about the benefits, use and duration of enrolment (Health provider_3).

A health provider from Mekelle hospital shared her personal counselling practice, saying "I cover each and everything about the nutritional support and other issues". However, she also acknowledged variations in the practice of nutritional counselling among health facilities and even between health providers in the same health facility.

Most participants received counselling mainly on the nutritional support and on dietary practice and hygiene to a limited extent. Counselling around the Plumpynut/sup included the benefits and proper methods of consumption, and its impact on weight gain and overall health status. In addition, issues around sharing or selling of the nutritional support and consistent use of the nutritional support were included. Adults and caregivers also reported that the importance of adherence to ART medication was covered during the nutritional counselling:

They [health providers] told me that the Plumpynut is more important than any medication and they advised me to take it properly. They also told me selling is illegal which may lead to penalty or imprisonment¹⁰. It is also not to be shared with children and wife (Adult male, age 32_21).

¹⁰ This does not mean imprisonment, but I think the health providers were trying to warn participants that selling the nutritional support is forbidden.

Counselling for caregivers about the nutritional support had a core focus on sharing practice and its consequences. This was principally because some health providers believed that sharing concerns were more common in children than adults, as detailed above. A caregiver described her counselling experience about sharing.

The health providers also told us not to share the Plumpynut with healthy children who it is not prescribed for (Caregiver, Age 35_10).

Limited information was provided to adults and caregivers regarding dietary practice, hygiene and sanitation, and minimising stress during nutritional counselling. The importance of consuming cooked foods and addressing food safety issues were reported as elements of nutritional counselling:

They tell us to diversify our foods as much as we can and to eat as much as possible as we can even if we didn't have a good appetite (Adult male, age 54_7).

An HIV positive caregiver previously enrolled in the nutritional program herself described her experience of the nutritional counselling regarding dietary practice:

They teach us to consume balanced food, and we should eat balanced food which is available at home. We have to take small and frequent meals. We shouldn't eat everything at the same time. They had also taught us to eat diverse food (Caregivers, age 39_7).

Hygiene, to drink clean and safe water and to use Woha Agar (water treatment) to treat the water or boil it (water) before use, otherwise I didn't remember any specific counselling session (Adult male, age 50_6).

They always counsel us not to get stressed but sometimes it is difficult to avoid stress. So, if you get balanced food and avoid stress, there is no reason that your weight will decrease (Adult female, age 31_1).

The other topic covered in the counselling sessions in a very limited extent was regarding food and ART medications. Health providers stated that many people living with HIV believed that patients on ART needed special food. Some participants recalled discussions on food consumption while on ART as part of the counselling process. Despite the nutritional counselling about ART and food that emphasised the consumption of available food when on ART, many adults and caregivers still held the belief that patients on ART needed special food.

About our dietary practice, they told us to take foods that goes with the ART medication such as eggs, meat and milk. As I told you about that, if you have enough you will eat, if not you will use whatever you have with the ART (Caregiver, age 48_16).

Applicability and acceptability of the nutritional counselling

For those adults and caregivers who had received counselling, most reported that they had implemented what they had learned about the nutritional support, hygiene and other dietary issues in their daily practice. Applying the nutritional counselling helped to improve knowledge, weight and health status for those participants. Both adults and caregivers reported that counselling sessions assisted them to learn about the importance of not fasting (details about fasting and the nutritional program is stated in sub-section 5.7.3), personal hygiene, and the use of nutritional support as per the health providers' recommendations:

She [the health provider] advised me not to fast while I am prescribed with the Plumpynut. After that I accepted her advice and I am not fasting at all (Adult female age 30 4).

I fully practice the counselling advice because I understand that all the benefits of counselling are to improve my weight. When they counsel you, they are helping you not to get sick and weak. Everything that I am getting here is giving me life so that I am able to work and support myself (Adult male, age 34_13).

Some health providers expressed concerns that information from the nutritional counselling was not well accepted by some patients, particularly by older adults. This was believed to be partly due to the lack of understanding of the benefits of the nutritional counselling:

Had it been that they apply all the counselling services given to them like the ART medication, they may get the necessary benefits from the nutritional program: as well we may not have default or loss to follow up from the nutritional program (Health provider_1).

However, where nutritional counselling had a narrow focus only on the use and benefits of the nutritional support, this was less commonly raised as an issue affecting acceptability, but it was a critical challenge for applicability of the nutritional counselling. In addition, food insecurity was a challenge for nutritional counselling and will be discussed in detail in the sociocultural factors section below.

Barriers to effective nutritional counselling

There were several barriers for the health service in implementing nutritional counselling in HIV care. In general, lack of training and training materials for health providers, absence of nutritional counselling guidelines, and uncontextualized nutritional education were the main barriers to effective nutritional counselling in the nutritional program in HIV care settings.

The lack of socioeconomic considerations, irregularity and inconsistency of information given to patients were also another barrier to the effectiveness of the nutritional counselling. Adults mentioned the inadequacy of nutritional counselling as the main challenge in understanding the nutritional program and its benefits but it was inadequate in relation to addressing broader socioeconomic conditions. Health providers also related the challenges of nutritional counselling to patients' lack of understanding of nutritional counselling and nutritional programs.

To make the nutritional counselling effective, an assessment and consideration of household socioeconomic status was crucial. However, most participants reported a lack of such consideration during nutritional counselling. Dietary recommendations were provided with little consideration of the socioeconomic conditions under which patients lived. Such issues were noted by an adult participant:

They didn't say about this [household socioeconomic status]. They didn't ask about what we have and haven't. They only tell us to diversify our dietary practice. There is nobody who knows about our household status (Adult female, age 36_19).

In addition, because of the medicalised nature of the nutrition program, the nutritional counselling where it existed was mainly about the nutritional support.

Despite the counselling advising food diversification and ways to improve food consumption, for some participants poor access to adequate food was a key barrier to fulfilling the key messages promoted in nutritional counselling.

5.5.4 Previous history of enrolment in the nutritional program

Nine out of 20 adults and three out of fifteen children had previously been enrolled in a nutritional program. Interviews with these adults and caregivers revealed the association between prior involvement in the program and its outcomes with how they currently used the program. In most circumstances, previous enrolment and recovery in the nutritional program contributed to higher adherence to the program in their current enrolment.

While a small number of those who had previously been enrolled in a program reported using the nutritional support as prescribed, others reported some misuse in their previous enrolment. Such misuse involved sharing, selling or not using nutritional supplement regularly as prescribed because of the absence of appetite and lack of understanding. Some adults reported a history of enrolling in the nutritional program almost every year.

Most patients with an experience of prior enrolment reported that their previous enrolment had improved their understanding of the program and appetite and thus helped them to better comprehend and utilise the nutritional program.

During my first enrolment, I didn't know about it at all. While I was supposed to take two [sachets of the nutritional support] per day I was taking three or four per day. But in the second and third enrolment, I take it [the nutritional support] based on the recommendations of the health provider (Adult male, age 47_22).

I was not strict when taking the previous Plumpynut because I was not too sick at that time. It was at the beginning of the Plumpynut but I didn't understand whether my weight had increased or decreased (Adult male, age 52 5).

Adults and caregivers with an experience of nutritional recovery in their previous program enrolment also had a positive influence on other patients currently enrolled in the nutritional program. As peers who shared the same problem in terms of positive HIV status and enrolment in the nutritional program, positive peer experiences were more trusted and acceptable.

Previous recovery in the nutritional program was a good lesson for adults and caregivers on the benefits or proper use of the nutritional program. It was an experience to which many brought positive prospects about their current enrolment in the nutritional program. While previous enrolment and nutritional recovery was a good foundation for proper utilisation during the current enrolment, it was also a prediction of the effectiveness of the nutritional program in HIV care in terms of sustaining weight.

5.5.5 Experience of the health service

In the previous sections, motivation for enrolment in the nutritional program and experiences related to the nutritional counselling were discussed. In this section, how participants' experiences with the health service and its influence on the utilisation of the nutritional program will be explored.

Participants shared their experiences of the health service in general, their adherence to the nutritional program, quality of services, experiences of nutritional assessment and monitoring and patient–provider relationships. Health providers contributed further comments on health service issues that posed challenges for the utilisation and success of the nutrition program in the HIV care service.

Experience of HIV care services

The themes which emerged from interviews in relation to HIV care services included waiting rooms, service delivery, location of HIV clinics in relation to other service areas in the hospitals, and the availability of equipment such as weighing scales and measuring tapes for anthropometric measurements. HIV clinics in all hospitals were located away from other service areas in an effort to ensure HIV patients' privacy. Similarly, HIV clinics' waiting rooms in all hospitals were considered suitable because they had adequate numbers of chairs for seating and a television, and they were conveniently located or easy to find. The ART pharmacy was located with other pharmacies at the exit of each hospital but this did not always ensure confidentiality. All HIV clinics had functional equipment necessary for the nutritional programs and other HIV services.

A positive experience of the general health service led to a more positive assessment of the nutritional program more generally. Adults and caregivers shared their experiences of ART, the nutritional program and other services provided at HIV care clinics. ART medication adherence was positively noted as contributing to their own and their child's health and wellbeing. The majority of participants believed that the provision of free ART medication facilitated access to HIV services and improved health outcomes such as higher CD4 counts, weight gain and return to work. During ART appointments, adults and caregivers reported that their weight, body mass index and mid upper arm circumference (MUAC) were always measured. All participants confirmed the regularity of nutritional assessment and monitoring in all health facilities.

The cost of accessing services and medications other than HIV was reported as a concern in Mekelle hospital but there was no mention of such concern in other hospitals. This might be because of the differences in the operation and implementation of the HIV service in general and the nutritional program, for example, resulting from differences in qualifications and experience of health providers.

...They [health providers] provide us the ART medication for free but if you are sick due to other illness, they send us to buy the medications outside in a private pharmacy which is very expensive and difficult to afford instead of providing us inside the government hospital (Adult female, age 45 2).

In addition, adults and caregivers felt that the provision of counselling and other supports provided by health services and providers to people living with HIV have been reduced in extent, level of detail and persistence had decreased over recent years because HIV infection is being considered more as a simple and non-fatal condition. In addition, health providers reported that follow up and monitoring of HIV services such as ART and others were also affected.

The current service has problems because previously if there was a malfunction of CD4 machine, it was repaired immediately but if it malfunctions now, they will not fix it immediately. Previously, there was no interruption in the ART but now, the ART medication is very much interrupted. So, while you are telling clients not to interrupt the ART medication, they may interrupt because of lack of ART medication in the health facility (Health provider_6).

Perceived quality of service

Perceived quality of the service had an impact on participants' experiences of the nutritional program and was to related to service integration, waiting time, health providers' experience and skills as described below.

Service integration: Issues around integration emerged at both service and program level. Integration of the nutritional service into other HIV services, including appointment dates, service venues, monitoring and follow up was believed to foster utilisation. Adults and caregivers reported a combined appointment date to collect ART medication and nutritional support as a factor facilitating program utilisation. In addition, where the nutritional and other HIV services were provided by the same person in the same room also promoted positive utilisation.

However, some challenges constraining service integration were noted. For example, in Mekelle hospital, two adult participants indicated nutritional services were provided in a different venue and by different providers than other HIV services. Another issue was in relation to using different registration books for monitoring individual patients for different services, which may overburden health providers and compromise the quality of the nutritional program. The frequency of visits required to receive ART medications was every three months while participants needed to attend the health facility on a monthly basis to receive their nutritional support. This misalignment was reported as having a negative effect on adults and caregivers' utilisation of the nutritional program, as indicated by a health provider:

The things they didn't like is that they can take the ART medication every three months if they want and it is allowed for about three months but the Plumpynut is not. The maximum is monthly, but every two weeks is best for adherence as per the protocol but since there is distance problem, it may be difficult for them to come every two weeks. Many even complain about the monthly schedule due to transportation issues (Health provider_9).

At a program level, lack of integration was noted by program managers. One of the key challenges was the lack of integration in the design and implementation of the nutritional and other HIV programs. Similarly, other health providers added that even though there are nutrition programs for both adults and children living with HIV, these programs were not governed by the same department at a programmatic level. This lack of programmatic integration contributed to service fragmentation and constrained nutritional service utilisation:

There shouldn't be separate activities in the different departments. They should work together to address a certain problem. This is one gap: there is no integration between the two departments (nutrition and chronic HIV care). Because, you will go down to the facility level and you will talk about HIV nutrition, people working in MCH will also go to the facility level to address under five or MCH nutrition (Program manager_1).

In summary, the health system used different resources such as human power, scheduling and reporting formats to monitor, supervise and follow the nutritional program and other HIV programs. In the above, the use of different registrations (logbooks) for the nutritional program and other HIV services was noted, which was a reflection of problems of programmatic integration. This may lead to over-extending the health system and services, with direct and indirect effects on the utilisation of the nutritional program.

Waiting time in the health facility: Because adults and caregivers visited the health facility every month for three to six months to collect the nutritional support and undertake nutritional assessment, monitoring and follow up, waiting time was an important factor affecting program utilisation. However, overall, waiting time was not a major concern for participant.

I don't have any problem with this regard and the health providers always treat me properly. When I come on my appointment date, they serve me as quickly as possible. There is no delay at all (Adult male, age 40 18).

A small number of interviewees did report frequent delays in being seen.

...the waiting time, there is a long waiting time, and this puts pressure on our daily activities (Adult male, age 52_5).

Health providers' experience of and skills in the nutritional program: Despite general acknowledgment of HIV services, some participants reported inexperienced health providers as a barrier to program adherence leading to default from the nutritional program. The lack of consistency in patient care including nutritional assessment, monitoring, follow up, and counselling was reported as being the result of providers being inexperienced and was considered a barrier to the utilisation of the nutritional program:

At the beginning I was not told anything about. As I told you I stopped the Plumpynut, because I didn't know that I was throwing all the Plumpynut sachets I consumed. After I stopped it, they saw it in my third visit and they realize that I am taking Plumpynut. I told them that I didn't know that I will take it again (Adult female, age 31 1).

Similarly, health providers acknowledged the lack of experience of some staff members during patient assessment, classification and prescription of the nutritional support.

There are some gaps in this regard from the highest to the lowest level health providers. This is my observation. For moderate malnutrition, Plumpysup is given as per the guideline but there are times where Plumpynut is given. Again, while the patient has severe malnutrition, some health providers prescribe Plumpysup but Plumpynut is recommended. So, there is problem in identifying the difference in content between the two (nutritional supports) (Health provider 10).

This was seen to be related to the lack of continuous refresher training, support and capacity building for health providers which will be discussed in detail in the section examining health system factors.

Service strategies to improve adherence

Health facilities employed different strategies to improve nutrition program adherence rates. These included continuous nutritional assessment and monitoring, encouraging patients to return empty sachets to the service, use of case managers (people living with HIV trained as ART adherence counsellors), peer education and use of the regional regulatory body¹¹.

Continuous nutritional assessment and monitoring to determine the HIV patient's response to the nutritional program was one strategy used to monitor adherence. Based on changes in BMI, health providers decided on the counselling requirement, duration of follow up, and the next ration. However, a health provider from Mekelle hospital indicated problems following a reduction in the frequency of patient monitoring and follow up because of the decreasing level of attention being paid to the nutritional program by health providers and patients. Another mechanism used to ensure adherence to the nutritional program was making people return the empty sachets to the health facility.

If he is adult, we measure their weight at each visit and assess their improvement. So, we can monitor him [the patient with HIV's progress] by this means. The other mechanism we use is we ask them to bring the empty sachets. So, if they didn't bring the empty sachets, then that means we can suspect that they are giving it to others (Health providers 3).

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¹¹ Regulatory is a regional body which control and regulates the nutritional support and other drugs in Tigray region.

However, some caregivers were not aware of the reason for returning empty sachets to the health facility:

I really don't know that because they didn't tell me about that, rather they told me that I have to bring an empty sachet back to the health facility (Caregiver, age 31_5).

Another mechanism, as cited by a health provider from Mekelle hospital, was the use of case managers to trace defaulting adults and caregivers. However, home visits to track adults and caregivers have recently ceased because of financial constraints and the lack of support from non-government organisations in HIV care in general, such as paying compensation for tracing workers.

The case managers also, didn't come on the appointment date, actually it is not there now but they were paid to trace them [adults and caregivers] by the NGOs in order to help them come to the program (case managers) during their home to home visit (Health provider 11).

Peer education was another mechanism used to improve adherence to the nutritional program, according to a health provider.

The other way is to use their peers to counsel and monitor them to see if they are using it properly. We tell the case managers (trained peers) to monitor them if they are taking it to local shops to sell or not. So, this will have an effect on the outcome (Health provider_4).

At the regional level, working with the regulatory body and establishing a task force were reported as mechanisms mainly to control selling of nutritional support. Task forces are groups of people established from different sectors to control selling of the nutritional support. These task forces were from the hospital or other health providers, district health regulators, police and from other relevant sectors.

The regulatory system works on Plumpynut and other drugs to control their mis-use. We do all these together with regulatory based on the gaps coming from the lower facility level such as woreda and zonal level we work to control selling (Program manager 1).

5.6 Broader health system factors

This section presents the broader health system factors that facilitated or constrained the utilisation of the nutritional program. These overlaid some of the health service factors highlighted above. A comprehensive understanding of these factors assists in enhancing program effectiveness through addressing broader health system challenges. The key themes that emerged in this study included access and availability of the nutritional program, program design and implementation, and workforce issues (**Figure 5.1**).

This study found that the accessibility and availability of the nutritional program at a broader health system level in terms of physical access, funding, and supply of the nutritional support created tremendous challenges to utilisation of the nutritional program. Decreasing interest among national and international partners and donor organisations has resulted in a reduction in funding for HIV care in general and the nutritional program in particular, and in turn this has affected the quality of the current services. This contributed to the interruption in the supply of nutritional support, inadequacy of staff training, patient monitoring and follow up. Program implementation issues such as workforce, program scope and sustainability monitoring and implementation were other factors affecting program effectiveness.

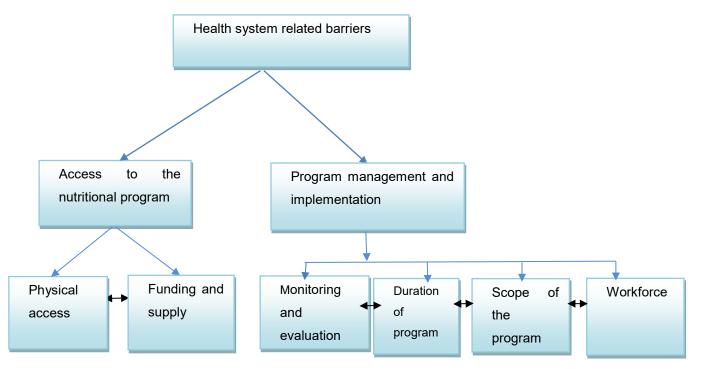


Figure 5.1: Schematic presentation of health system factors

5.6.1 Access to the nutritional program

Physical access to the nutritional program

Participants enrolled in the nutritional program were required to visit a health facility every month for three to six months depending on their initial nutritional assessment. In such circumstances, physical proximity to the nutritional service was crucial for the program utilisation.

Despite the relative decentralisation of ART distribution, the nutritional program, particularly nutritional support services, are provided in a more centralised manner. Many participants had to travel long distances to reach the nutritional service and lack of affordability of transport services was noted as a barrier constraining access to HIV services. The quote below illustrates how transportation costs were worsening this participant's poor household socioeconomic status.

That [transportation fee] is my only problem because I don't have anybody to support me. I have to feed my kids, and no one is helping me. So, transportation is the most important concern when I come here (Adult female, age 37_16).

My problem is the transportation fee. I can't walk on foot and I have difficulty to get transportation. I sometimes miss my appointment date because of lack of transportation money (Adult male, age 32_21).

All health facilities providing HIV care conducted nutritional assessment in the Tigray region. However, only a limited number of health facilities provided a comprehensive nutritional service which included nutritional assessment, counselling and nutritional support. Other facilities only conducted nutritional assessment and counselling and referred patients to other health facilities for nutritional support, requiring people to travel for this aspect of the program.

The other thing we faced is that also, there are users from far places such as Alamata, Ofla, so since the Plumpynut is given for about a month but the ART medication is given for about 2-3 months. So, since they are coming to take the Plumpynut every month, in fear of coming every month they refuse the Plumpynut even though they are malnourished (Health provider_6).

Furthermore, since 2015 the number of health facilities offering a comprehensive nutritional service has been reduced from 64 to 21 in Tigray region, and the remaining sites were those with large caseloads.

The current problem in the nutritional program is the coverage. Previously the coverage of the nutrition program was good including the supply. It was provided in many health facilities so that the individuals categorised as SAM and MAM were getting the nutrition related support (Plumpynut/sup) and service in their nearest possible health facility. But, nowadays it is limited to the facilities with the highest number of clients mostly in hospitals (Program manager 2).

Most adults and caregivers could not afford the transportation costs and some could not walk the distance because of impaired health status. In addition, many adults, mainly males enrolled in the Shul hospital program, were in temporary jobs and had to move to places with no health facilities. This was reported by health providers as a common reason for defaulting from the nutritional program in Shul hospital.

There are many defaulters because some went to traditional gold mining and farming. But the nutritional program doesn't consider this when a patient moves to other places because different activities. It is given to everybody with BMI <18.5 despite their economic status (Health providers 1).

Another transportation challenge reported by participants was transporting the nutritional support from the health facility to their home. The nutritional support was bulky to transport for adults and caregivers who had ailing health status. Neither the health service nor the health system provided any arrangements to deliver the nutritional support. However, some volunteers from associations of people living with HIV provided transportation support but this was often in a fragmented, disorganised and irregular manner:

There are volunteers who helped us in every respect including transporting the Plumpynut. In my case the volunteers helped me to take the Plumpynut to home because I was too sick to carry even my hand bag (Adult female, age 45_2).

Funding and supply of the nutritional support

Non-government organisations (NGO) in Ethiopia play a crucial role through partnerships with the Ministry of Health in the funding, implementation, monitoring and supervision of health programs such as the HIV care service and nutritional program. International NGOs mainly focus on the procurement and distribution of the nutritional support and provision of necessary equipment for the nutritional program. In addition, they play a fundamental role in the implementation of the nutritional program by providing training to health providers and other staffs, monitoring and supervision. However, it was noted that NGOs have begun to withdraw from these contributions.

There were many partners (NGOs) previously working in HIV programs and they were providing many supports to the health facilities including logistic and technical support but not now (Health provider_4).

From the viewpoint of some health providers, the withdrawal of international has resulted in the slowdown of HIV services, including a reduction in the supply of medications, nutritional support and other financial supports, decrease in the frequency of health provider training, and program monitoring and supervision.

There were many NGO partners previously but now it is not as it used to be. I don't know the reason specifically but there are circumstances where we can't get ART medications. So, we have HIV patients who default from the ART medication due to the lack of ART medication in our facility (Health provider_6).

The previous and current service may vary greatly in my view. Most HIV programs are donor support programs and there is a clear decline in the number of NGOs working in HIV programs. They are withdrawing and handing over the program to the health care system (Health provider 1).

Local NGOs had also been providing additional support to people living with HIV after graduation from the nutritional program. This included financial support in the development of income generating activities and prevention of relapse of undernutrition.

Some local NGOs were involving many HIV patients who had graduated from the nutritional program in income generating activities. They were giving from 20-30 thousand birr loans in an effort to economically strengthen them. It is called a loan but finally if they are successful in supporting themselves, they are not obliged to return the money (Program manager_1).

At the time of the interviews, these support activities were very limited in scale and coverage. This decreasing involvement of local and international NGOs may influence the effectiveness of nutritional programs in HIV care. The quote below elaborates on the extent of current NGO involvement:

There were some NGO/charity organisations supporting those who graduated from the nutritional program to not relapse. But now there are not too many charity organisations supporting graduates of the nutritional program. But we are still making an effort to link them [patients] to charity organisations which engages them in income generating activities (Health provider_1).

An adult male also reflected on the decreasing level of support from NGOs:

Previously, some foreign aid organisations were helping people living with HIV but there is no more such a thing and there are some people who are suffering from many problems such as lack of food to eat (Adult male, age 54_7).

The challenges associated with the funding and technical issues related to the distribution and management of supply make the continuity of nutritional support provision one of the key issues the nutritional program must contend with. This could be mainly related to the reduction of NGO involvement in HIV service in general and the nutritional program in HIV care.

Funding was a key health system issue identified by health providers and program managers. Participants referred to funding and budgets to the nutritional program coming from donor organisations but were not aware of the reduction in funding from the national and regional governments in Ethiopia. A program manager noted:

The screening service is provided everywhere [referring to nutritional assessment], but all hospitals and some health centres provide the service [comprehensive service] including the nutritional support but this year they [the service centres] have decreased because of the budget, the commodity of Plumpynut has decreased. So, only 21 facilities provide treatment [nutritional support] (Program manager_1).

Participants reported that the provision of nutritional support in all health facilities involved in this study had been periodically interrupted.

Yes, I was told that it [the nutritional support] is not available but it has been generally available. Since I started to take [Plumpynut], this is my first time to be told that there is no Plumpynut (Adult female, age 29 15).

It [the nutritional support] is for three months. It has been interrupted for one month, but it is now provided for three months. The Plumpynut was not available for one month and I was waiting (Adult male age 54_7).

The lack of continuous supply and frequent interruptions contributed to default and non-response particularly when they occurred during the continuation phase (second visit and later). A health provider noted:

Now it [the nutritional support] is fine but there were some interruptions of the Plumpynut before. While the patients are taking the Plumpynut, it gets interrupted. A person may be close to graduation then if the Plumpynut stock is not available, it will get interrupted. So, this interruption will influence adherence to the nutritional program and recovery of their nutritional status (Health provider_7).

5.6.2 Program management and implementation

A number of elements in the management and implementation of the nutritional program emerged as affecting program utilisation. These were program duration, integration, monitoring and supervision and sustainability of the nutritional program.

Duration of the nutritional program

Total duration of the program, from enrolment to discharge, emerged as an important element influencing nutritional program utilisation. Many participants had no clear information about the duration of the nutritional program. Those who had graduated reported being enrolled in the program for at least three months and a large number of them felt that the nutritional program had been stopped too early.

They shouldn't tell you to stop in your second visit because the weight gain may be lost again. If it is stopped at the fourth visit, it is alright, and your weight may not come down (Adult male, age 52 5).

During the process of implementation of the nutritional program, health providers reported that its duration was three months for moderate undernutrition and six months for severe undernutrition as per the guideline. However, some health providers believed that this time was too short for some adults and children living with HIV to recover from undernutrition:

There are some who don't show much change or improvement in their weight. Because they are below severe undernourished individuals and when you give them the Plumpynut, they don't recover as it is supposed to be in the given period (Health providers_1).

Monitoring, supervision and evaluation of the nutritional program

Some health providers believed that the nutritional program did not have adequate 'ownership' in the existing health system and lacked proper monitoring and supervision.

We only go according to our knowledge. If there is something new in the program, no one tells you about it. There is no sense of ownership of the nutritional program. So, there should be an ownership to the program. There should be monitoring, mentoring and supervision of the program in order to benefit the patient (Health provider 7).

Lack of ownership of the nutritional program in the HIV care setting related to the absence of adequate and proper integration of the nutritional program into other HIV programs and decreasing NGO involvement. Problems of service integration in the program demanded extra human and financial resources for monitoring and supervision of the program, which may have imposed an additional burden on the health system. The reduced level of NGO financial and technical support had made monitoring and supervision more difficult.

The lack of proper monitoring and supervision was seen as a factor hindering the identification of program gaps, training of staff and follow up.

...there is no body to monitor and supervise the nutritional program. It is not like other programs with good support and supervision. Even if they come to monitor and supervise other HIV programs, they usually leave it suspended. They didn't give us comprehensive monitoring and feedback (Health provider_4).

One program manager noted the importance of information gained from program monitoring and supervision for identifying service gaps and training requirements for health providers. Although health managers stressed the collection and use of comprehensive sources of information from individual patients, health providers and health services to monitor, supervise and evaluate the nutritional program, they were unable to present any reports or tools that they had used for monitoring, supervision and evaluation.

Scope and sustainability of the nutritional program

The nutritional program in HIV care settings focused on individual patients, based on anthropometric parameters such as body mass index and MUAC. In this way, the nutritional program and nutritional support mainly addressed the nutritional issues at clinical and individual levels. Interviews with adults, caregivers and health providers revealed that people enrolled in the nutritional program suffered from broader socioeconomic problems that were not clearly considered in this program (discussed further below). In addition, the narrow focus of the nutritional program only on the individual index patient ¹² was a huge challenge for the effectiveness of the nutritional program in the presence of food insecurity as indicated by a health provider:

When one household head has the disease HIV, the children in the household are also likely be affected nutritionally. This concerns me a lot. We are treating HIV positive patients only, but we are not including those who are affected due to the illness of the household head. Because she/he may have dependent children under her (Health provider 9).

In addition, the nutritional program has a very limited follow up plan for participants who have graduated from the program. Follow up is particularly important to maintain good nutritional status and prevent further relapse. Health providers stressed the necessity of linking graduated adults and caregivers to income generating activities. Health facilities like Mekelle hospital reported doing this on a limited scale. In addition, program managers added the availability of initiatives such as back to work initiatives to strengthen the economic status of people living with HIV:

The major issue that creates a problem in this regard is that when they graduate finally from the nutritional program there should be some sort of support for not to relapse again. So, there are limited efforts made to prevent relapse of malnutrition after nutritional recovery (Health provider_2).

However, these initiatives were seen as limited in reach and were not able to involve large numbers of people.

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¹² Index patient is the primary target of the nutritional program.

Program sustainability emerged as a crucial issue in the nutritional program. The key points noted included a reduction in the level of support provided to HIV patients mainly due to the lack of basic medication, poor financial support and a reduction in frequency and intensity of ART adherence counselling. In addition, the recurrent interruption of the nutritional support was another source of sustainability concern for adults and caregivers.

It used to be before, but there is no kind of support. Nowadays, we are getting ignored by the government (Adult female, age 44_2).

Health providers and program managers shared the concerns of adults and caregivers about the sustainability of the nutritional program. Health providers noted the importance of intensification of the nutritional program:

The major challenge I see is the sustainability issue. This nutritional program is very important and saving many lives of HIV patients on ART. As far as there is poverty and food insecurity, it is good to support HIV patients nutritionally. Even though there are misuses, it has great benefits to the HIV patients (Health providers_1).

However, regional program mangers were certain about the sustainability of the nutritional program because it was currently operating as part and parcel of the HIV care program in particular and the health system in general.

Workforce issues and the nutritional program

Health providers highlighted the inadequacy of the workforce in the HIV care and nutritional program in terms of number of staff and the provision of necessary training. It was believed that all HIV care service areas were overloaded with people living with HIV and there were insufficient health providers to offer the service. Because of the small number of health providers compared with the patient load, the time spent providing nutritional counselling, proper monitoring and follow up of adults and children enrolled in the nutritional program was compromised.

Health providers reported that training about general nutrition that was given with ART training had small sections of nutritional counselling.

During the ART training, there was a section about nutrition for HIV patients. What the counselling session looks like, the training is given to all professionals always. There is no separate guideline. But it is together with the ART training. Even when we assess about adherence, there is a nutrition section in it (Health provider_8).

However, health providers confirmed the inadequacy of staff training in terms of frequency and content. A limited number of health providers working in the nutritional program obtained training about the nutritional program and the others offered the service based on their general knowledge of nutrition:

Issues related with the health system, one is the professionals. In order to give good service; their training should also be good. The health professionals should know the contents of the two food supplements (Plumpynut and Plumpysup). The knowledge of the health provider is low (Health provider_10).

Lack of basic and refresher training to maintain uniformity of the nutritional counselling among health providers significantly contributed to the challenges of the nutritional counseling. This was believed to contribute to inconsistencies in implementation, monitoring and patient follow up. On the other hand, the program manager did not agree that training about the nutritional program was inadequate, claiming that training to rectify knowledge gaps and general training were provided on a regular basis.

5.7 Socioeconomic and cultural factors

Participants identified a range of socioeconomic and cultural factors including food insecurity, poverty and poor livelihood, the cultural meaning of the nutritional support, religious and cultural experiences, stigma and discrimination, and transport and distance as key factors influencing utilisation of the nutritional program.

5.7.1 Poor livelihood, poverty and food insecurity

Poverty and food insecurity were identified as an important challenge for HIV patients enrolled in the nutritional program. Many adults and caregivers reported loss of jobs and lack of employment opportunities because of their prolonged illness, and the loss of productivity. In addition, stigma and discrimination limited the employability and job opportunities of people living with HIV, which in turn contributed to deepening poverty and poor livelihood.

I live in rural areas and it is beyond my capacity to work in rural areas [farming]. I can't stand the work [activities to live on] in rural areas. In urban areas it is possible for me to do some jobs. But I can't work labour intensive activities (Adult female, age 36_19).

Moreover, large numbers of adults and caregivers had little or no educational attainment and minimal skills. This limited their chances of obtaining a secure income. Thus, lack of regular and reliable employment, and absence of sustainable and reliable income to support them and their family contributed to poverty and poor livelihood for people living with HIV.

If you are poor and don't have a good job, even if you try to create your own job, no one allows you to work because of no education. I asked the Kebele administration for a job, but they told me that you have no education. This makes you very angry. Otherwise if you have a job, you will eat adequate and balance food. (Adult female, age 31_1).

I and my husband are daily labourers. So, we may not have enough in our home and we have also three HIV negative children who share the household income equally (Caregiver, age 35_10).

Addressing poverty and poor livelihood was crucial to improve and sustain the nutritional wellbeing of people living with HIV enrolled in the nutritional program. Adults indicated the presence of support for people living with HIV from rural areas, such as provision and maintenance of land, and initiatives prioritising adults in any income generating activities, but no such opportunities were reported by people living with HIV in urban areas. This may be a local government policy for all people living with HIV but people living in towns do not own land and there are no benefits in urban areas such as a social safety net.

In addition, providers claimed that some adults and caregivers did not want to graduate because of their poor socioeconomic status, because being in the program provided them with a chance to receive, and in some cases, sell nutritional support to fulfil their household needs.

It is because of their poor economic status that most don't want to graduate. If he graduates, you will not give him Plumpynut in the next time because they don't have other sources of income. Most want their weight to stay as low as possible (Health provider 7).

Many adults and caregivers enrolled in the nutritional program reported the lack of access to adequate food as the main reason for their weight loss, highlighted above. As noted previously, household food insecurity also led to sharing of the nutritional support with children and other family members:

I am not taking adequate food and even now, I can't get enough. I give everything I have to my children and I emphasise feeding and caring for them. With the problems I have, I can't get enough food to support myself and my children (Adult female, age 29_15).

Even though it is prescribed to the sick child, if there is no adequate food to eat in the household, the mother may share it with other children. So, the mother shares it to fulfil the dietary needs of the other children in the household because she has nothing to give to the other child (Caregiver, age 35_9).

Food insecurity not only influenced the immediate nutritional outcome (nutritional recovery) but also created the risk of relapse of undernutrition if participants were sent back to food insecure households after nutritional recovery. Household food insecurity seemed to sustain the vicious cycle of undernutrition in adults and children enrolled in nutritional program, affecting program effectiveness (**Figure 5.2**). This again highlights the narrow focus of the nutritional program on individual anthropometric measures, as described in the health system related issues in the previous section.

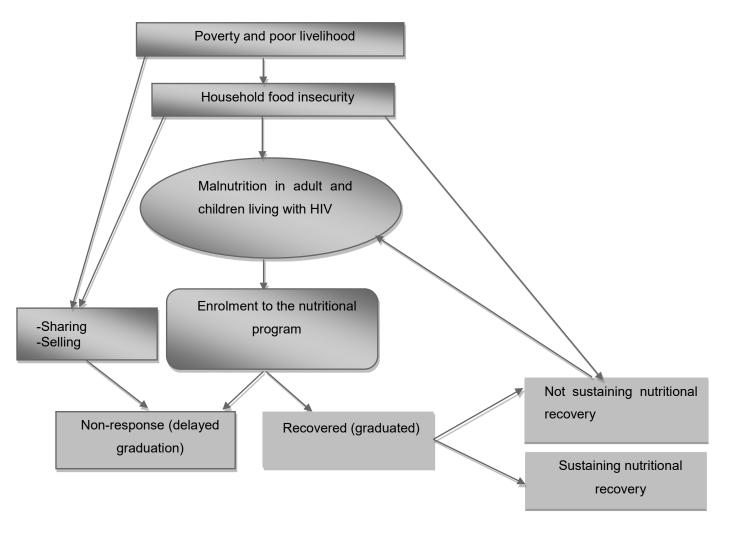


Figure 5.2: Depicting vicious cycle of undernutrition and the nutritional program in HIV care program in Ethiopia.

5.7.2 Cultural meaning of the nutritional support

Differences between the nutritional support and local food were reported by most adult participants and included taste, packaging, and the method of preparation. These differences hindered utilisation of the nutritional program.

The meaning of food is culturally constructed in Ethiopia. Food is seen as a social networking opportunity because people share a common dish at most meals in Ethiopia. Therefore, some study participants were reluctant to consume the nutritional support:

They [adults and caregivers] refuse to take generally packaged foods [referring to the nutritional support]. Even if we try convincing them, they usually relate it with religion and didn't take the food (Health providers_10).

There was no cultural practice that specifically hindered the use of the nutritional support, but it was less acceptable for adults because of the packaging and preparation. The nutritional support, the Plumpynut/Plumpysup, was very different from local foods in its packing, taste and preparation.

Behaviourally when I see the HIV patients, they want to eat food spiced with red chilli powder (Health provider_9).

The other is people suspect any packed thing may have something inside it. So, this may result in refusal specially women are common (Health provider_10).

A small number of adults also reported finding it difficult to consume the nutritional support (Plumpynut/Plumpysup) because it was not acceptable to suck it from the sachet. Others reported a general perception in the community that HIV patients consume and use strange things such as Plumpynut/Plumpysup. This increased their discomfort about consuming the nutritional support. In addition, because stigma and religious factors are deeply embedded in the culture, they became interlinked with cultural meaning of the nutritional support.

So, there is general perception in the community that there is nothing that HIV patients don't eat [referring that people living with HIV can eat anything]. This makes you worried when taking the Plumpynut and other like medication. So, I can't eat the Plumpynut in the market place in front of people because most people may say 'what is this woman eating? (Adult female, age 45 1).

For others, they found the nutritional support problematic to use at the beginning but became more comfortable as time went on. For example, an adult male living with HIV stated the issues related to the acceptability and cultural meaning of the nutritional program in the course of enrolment in the nutritional program:

At the beginning, I disliked it [the nutritional support] because it is very different from what I used to eat at my home (Adult male, age 29 8).

Health providers reported some religious practices, for example fasting, presented a barrier to the acceptability of the nutritional support. It was partly due to the packaging and a lack of understanding and knowledge about the contents of the nutritional support that made adults suspicious about the religious acceptability of it. This indicates the link between the cultural meaning of nutritional support and religious issues, discussed below.

According to caregivers, children face very few issues related to the meaning and cultural acceptability of the nutritional support as a food and some adults reported that they did not see any difference between the nutritional support and other local foods.

5.7.3 Religious experience related to the nutritional program

The interviews explored the ways that religious practices might influence the utilisation of the nutritional program. Religious fasting was stated as a major religious responsibility by a significant number of study participants. Most participants believed that not remaining true to religious fasting was a sin that led to further deterioration in HIV condition as God's punishment for violating the fasting.

Until the fasting time comes I have eaten, but during the fasting time, I stopped eating the Plumpynut to fast and store my Plumpynut until fasting breaks. (Adult female, age 31_1).

Wednesdays and Fridays were religious fasting days when the people living with HIV were not allowed to consume the nutritional support.

About fasting, I usually didn't take the Plumpynut on Wednesday and Friday. I also didn't eat during the fasting for Easter. So, except Wednesday and Friday I usually continue to eat the Plumpynut on the other days because of the ART medication (Adult male, age 29 8).

Some caregivers also expressed feelings of guilt for giving the nutritional support to their children during fasting periods. According to caregivers, while their children would like to fast because of peer influence, they usually encouraged their children to consume the nutritional support during fasting, but children had less religious obligation to fast than adults.

She says to me that she wanted to fast and wanted to go to church. But I say to her to take the ART medication and take the Plumpynut which I shouldn't do. (Caregiver, age 14_9).

A small number of participants felt that their health status was a priority over religious practices and consequently they used the nutritional program regardless of fasting.

With religion, now [referring time of interview] it is an important fasting time, but my health is more important. If I stay healthy, I can fast another time (Adult female, age 31 1).

Others reported that even if they believed in the religious importance of fasting, they consumed the nutritional support during the fasting time in consultation with their priest. Some participants suggested that breaking the fast was acceptable if the individual confessed and the faith leader pardoned them. Conversely, other people living with HIV believed that even in the presence of confession and pardon, it was a sin to consume the Plumpynut which contained non-fasting ingredients during the fasting period.

Health providers reported the negative effects of fasting on program utilisation. Default from the nutritional program was common among adults during fasting periods. In addition, fasting contributed to a significant number of non-responses to the nutritional program because of the interrupted consumption of the nutritional support.

There is also fasting. They keep it until fasting finishes and then they start it again after fasting break. When they default, and we ask them why they didn't come the previous month, they tell you that they didn't come because it was fasting. So, when they take it intermittently, they become non-respondent (Health provider 8).

Some health providers also supported the cessation of nutritional support during fasting which, more importantly, shows how strong religious beliefs are among people including health providers.

They usually took it but there are some who prefer to start the Plumpynut after breaking the fasting. But they continue to take it after the fasting time. I think this doesn't create any problem around the nutritional program (Health provider_3).

At the programmatic level, program managers reported the present policy directive for health workers was to counsel participants to discuss fasting with their faith leaders to improve utilisation of the nutritional program:

To a certain extent in relation with religion they are counselled in relation to fasting. We counsel them to discuss it with their religious father and to take the Plumpynut even during fasting (Program manager_1).

For those previously enrolled in the nutritional program religious fasting no longer affected their use of the nutritional support.

I fail to bring the empty sachets because I didn't eat it because of the fasting in my previous enrolment. But now, I continuously use it because my weight has been significantly improved from 36 to 40 kg (Adult female, age 31_1).

5.7.4 Stigma and discrimination

As has been alluded to previously, HIV status disclosure and associated stigma and discrimination emerged as an important theme affecting utilisation of the nutritional program.

Status disclosure

Participants provided various views in relation to disclosing their HIV status. A significant number of participants reported the disclosure of their HIV status to family members such as their partner, children, sisters and brothers, but they were not willing to disclose to others such as neighbours because of the fear of stigma and discrimination. The feared consequences of disclosure to people beyond family members were stigmatisation related to their business, jobs and social life:

If my neighbours know about me, it will have an influence on my work in the market. People don't come and buy from me if they know my positive HIV status. If this happens, it will have an influence on me and my children (Adult female, age 29_15).

Other adults and caregivers stated that they did not want to disclose their positive HIV status to anyone else including family members because they feared stigma and discrimination even from family members. An adult female living with HIV illustrated the reason for not disclosing her HIV status to anyone:

Yes, it is a problem, but I usually use it [Plumpynut] in front of them. When I am asked about it, I tell them it is given to me because I used to have TB. Even my elder daughter suspects me and asked if I have HIV, but I always convince her that I didn't have any problem. I didn't tell her because it could harm her psychologically (Adult female, age 31_1).

Another female indicated:

My brothers know my status, but everybody abandoned me once I got sick. Everybody is afraid of me because of my positive HIV status (Adult female, age 48_9).

A caregiver commented on the consequences of disclosure of positive HIV status of children:

Our neighbours didn't know about his HIV status, but my son said to me that children will not let him play with them. I don't know how the secret escaped. He refused to go to school because of this for three days (Caregivers, age 37 9).

Most children with HIV knew their positive HIV status but some children did not because of their young age and caregivers' concerns about the child's reaction to their positive HIV status and stigma.

While most did not wish to disclose their condition, a small number of participants had no problem with their condition being known by family members, local neighbours or even the broader community and did not perceive any negative consequences of disclosure of positive HIV status. Instead, they mentioned benefits of disclosure in terms of psychological, moral and sometimes financial supports from different individuals, neighbours, friends and families.

I am free with everybody and I didn't hide myself. Everyone knows about me. So, I have not experienced any problems so far. I don't bother too much not to be identified by anybody. In terms of support, yes, they provide me with support especially when there is support from Kebelle¹³ administrators (Adult female, age 37_16).

Since the majority of study participants lived in rental accommodation, being discovered by the landlord was a major concern. There was a perceived fear of being denied accommodation or use of shared toilets, bathrooms and other utilities by landlords in case of disclosure of their HIV condition. Social isolation and rejection by neighbours and the broader community was also a major concern. This was particularly important for children living with HIV who were likely to lose friendships and be rejected in play groups.

Let me tell you what happened while I was traveling by taxi last week. I was sitting next to a lady and I think she has a house to rent. She was telling her other friend that she suspects the person who rents her house has HIV, "I will send her out" (Adult female, age 31 1).

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¹³ Kebelle is the smallest administrative unit in Ethiopia.

HIV stigma and the nutritional program

Participants reported examples of being discriminated against as a result of their positive HIV status and engagement in the nutritional program. One health provider stated that experiences of stigma and discrimination presented a huge barrier to the utilisation of the nutritional program:

When the community sees them with the Plumpynut, they may be identified as HIV patients. If identified, it may result in loss of social network and connection (Health provider 1).

The relationship between the nutritional program and stigma and discrimination is related to the communities' perception about the nutritional program and fear of adults and caregivers fear of this perception. There are various perceptions regarding the nutritional program in the community.

Regarding community perceptions about the nutritional program, a small number believed that the community did not associate the nutritional support with HIV, so a fear of stigma associated with the food was not an issue:

The community may not associate it [Plumpynut] with HIV as I told you because it is available in local shops. But previously people used to associate the Plumpynut with HIV (Adult female, age _10).

However, most believed that the community associated the nutritional support with HIV at least in adults and this perception was also shared by health providers:

There are many who associate Plumpynut with people living with HIV and others say this is a food given for people who are weak due to HIV. Because there are many things the community associates with HIV (Adult female, age 29 15).

They [adult and caregivers] told me that they don't want to take the Plumpynut and they only want to use their own home made foods. This is because they don't want to be identified as HIV positive. Because if seen with the Plumpynut, they are afraid that they may be identified as HIV positive. (Health provider_6).

Because, the nutritional support was also given to undernourished HIV negative children, caregivers believed that the program was less related to positive HIV status in children.

Some people say to her why is she taking it because the Plumpynut is given to HIV sick persons. I told the children who ask her to say she is taking the Plumpynut because she is sick, that it is given to everybody who lost weight and has malnutrition and I tell them not to say her 'sick again' (Caregiver, age 28_6).

The program increases risk of exposure to stigma through the support and its association with HIV (eating in front of people required a longer time than taking medications, transportation and being seen with sachets, disposing of empty sachets) and increased health service visits.

The nutritional support (Plumpynut/sup) enhanced stigma during transportation and consumption at home. Because of its typical packaging, adults and caregivers transported it from the health facility to their homes hidden or covered with other bags even though it was bulky and not easy to hide, ranging from 10 to 20 kilograms for one month's supply, as stated by an adult and a health provider:

If some people know that you are using the Plumpynut because of your HIV status, there may be problems. So, people usually hide the Plumpynut during transportation and at their home especially when they live in a rental house (Adult male, age 54_7).

They [adults and caregivers] don't want to be seen while carrying [transporting from health facility to home] the Plumpynut box because it may result in their identification and further stigma and discrimination (Health provider 2).

Once take home, the nutritional support can enhance stigma in three ways. First, when consuming the nutritional support indoors or outdoors, adults and caregivers were afraid of being seen with the nutritional support because of its association with HIV and enhanced HIV stigma and discrimination. Secondly, because the nutritional support takes a longer time to consume than other HIV medications such as ART, adults and caregivers believe that the nutritional support provided greater risk of exposure. Finally, throwing away the empty sachets was more obvious than anything else, but currently all participants enrolled in the nutritional program returned empty sachets to be discarded at the health facility:

The nutritional support takes time to consume when compared with the ART medication, but I consume it at my home with great care. Even if I am out of home, I consume it after making sure that there is no one looking at me. Even when I am moving around, I also consume it but if there are people around me, I don't take it because it may expose me (Adult female, age 36_19).

It is due to the empty sachet thrown that our neighbours identified us and asked him why he is eating it at that time. So, my neighbours usually don't allow my children to play with them because they know our positive HIV status, as well as I told you, he has refused to go to school because the children in his school don't allow him to play with them (Caregiver, age 35 9).

Generally, for those who were concerned about the disclosure of their positive HIV status, finding a convenient place to consume the nutritional support was a challenge in most adults and some caregivers because of fear of being seen by neighbours and the neighbourhood.

When using, I close my door to use my Plumpynut and ART medication. I did this is to avoid stigmatisation. Because if they know, they will not allow me to rent their house or use toilets. So, if this happens I have nowhere to go. So, the only option I have is to use it like this (Adult female, age 29_15).

In addition to the nutritional support, the nutritional program more broadly also enhanced concerns of stigma and discrimination through increased frequency of visits to the health facility. Enrolling in the nutritional program increased the frequency of visits to collect the nutritional support and undergo nutritional follow up and monitoring. Compared with the frequency of visits for other HIV services such as ART, nutritional service appointments were more frequent. Thus, adults and caregivers were concerned about increasing the chances of being seen by someone they knew when visiting the health facility.

5.8 Nutritional program outcomes

In this section, the outcomes gained after enrolment in the nutritional program are discussed in terms of changes in dietary practice, weight gain and improved health and wellbeing, and retention in HIV care. It also illustrates the interrelationships between the different enabling and constraining factors highlighted throughout this chapter, and the individual outcomes gained by enrolment in the nutritional program. The nutritional outcomes of adults and caregivers are described in table **5.2**. Generally, how all factors influencing the nutritional program outcomes are interlinked is discussed below:

5.8.1 Improved knowledge of food, nutrition and available services

As noted above, counselling in the nutritional program focused mainly on the nutritional support (Plumpynut/Plumpysup). However, nutritional counselling also involved some elements of dietary practice, such as improving consumption and diversification of dietary consumption. Overall, there was an improvement in patients' knowledge and understanding about nutrition as a result of the program. A male adult HIV patient said that:

Some one's weight will increase if he eats well. If he eats well it is not his CD4 count that increases, instead, all his CD4 count and other things will increase. Even in order for his health status to increase, he has to get balanced food. If he doesn't get it right then he will get ill (Adult male age 47_22).

Similarly, the quote below describes the improved knowledge gained by an adult male participant:

The reason for this [improved weight] is that I used to take the medication properly and I am doing that currently too. But what brings the changes I have now is that I know what I should eat at home (Adult male, age 54_7).

However, participants' understanding of the nutritional service was mainly limited to the nutritional support (Plumpynut/Sup). This understanding emanated from the main focus of nutritional counselling on the nutritional support and because food insecurity was one of the motivations for enrolment in the nutritional program. In addition, lack of comprehensiveness and consistency in the nutritional program may also have affected adults' and caregivers' understanding of the nutritional program in HIV care service.

5.8.2 Improved appetite and dietary practice

As indicated in **section 5.3**, the perceived reasons for weight loss were food/dietary or non-food/non-dietary related. Being unable to eat well because of lack of appetite or access to adequate food were identified as the main perceived reasons of weight loss in adults and children. Almost all adults and caregivers reported that they had made positive changes to their dietary practices since enrolment into the nutritional program. The positive changes included improved appetite and eating well, effective use of available foods and drinking more water. Enrolment in the nutritional program in general enabled adults and children to eat better and more effectively and use other foods at home because of consumption of the nutritional support and nutritional counselling. For example, an adult stated:

After I took that [the nutritional support], I started to drink more water and take more other foods. This helped me to improve my weight and I am taking different foods in addition to the Plumpynut like milk, eggs and vegetables (Adult male, age 52 5).

Although improved appetite and dietary practice were achieved by participants in the nutritional program, poverty, poor livelihood and food insecurity were the main challenges that led to reversal of improvements in dietary practice and nutritional status. Religious factors such as fasting were another sociocultural factor contributing to poor dietary practices such as not eating animal products during religious fasting periods.

5.8.3 Improved weight, health and wellbeing

Concerns about weight loss and its effect on health and wellbeing were the main motivations for enrolment in the nutritional program for most adults and caregivers. Participants reported that they were weak and debilitated before enrolment in the program but gained weight and improved health and wellbeing after enrolment. In addition, approximately 50% of adults and 60% of caregivers reported that their or their children's' weight had increased, and their physical strength had improved during participation in the nutritional program. An adult female HIV patient attested the changes to her health and wellbeing:

Our health is fine since the introduction of this food [Plumpynut/Plumpysup]. I was unable to walk before I took the Plumpynut but now after taking the Plumpynut, I am fine, and my strength is good. I am able to support myself and collect and perform all my affairs by myself (Adult female, age 36_19).

In addition, a health provider noted the improved health and wellbeing of adults and children living with HIV:

I think many have benefited from the nutritional program and improved nutritionally, physically and their overall health" (Health provider_1).

However, some adults and caregivers attributed the weight gain only to the nutritional support and ignored the contribution of the nutritional counselling. This perception might be related to the ineffectiveness of nutritional counselling in HIV care settings. The nutritional support reversed acute loss of weight while the nutritional counselling was helpful for in terms of improving understanding about the nutritional program mainly about the nutritional support.

5.8.4 Retention in HIV care

ART adherence counselling was also part of the nutritional counselling in HIV care services. In addition, there was a widely held view among people living with HIV that ART needed food, and this was overcome by provision of nutritional support and nutritional counselling. The nutritional support addressed temporary food insecurity problems and also considered a reward for ART adherence by some adults and caregivers. Despite the ineffectiveness of the nutritional counselling, it was able to address some concerns of adults and caregivers by clarifying that ART could be taken with whatever food was available at home.

Nutritional support played a vital role for adults and caregivers who, because of their illness or undernutrition, were unable to walk to a health facility to collect ART medication. Improved health and wellbeing after enrolment in the nutritional program allowed adults and children to walk to the health facility and adhere to their appointment dates. Thus, the nutritional program essentially helped ART adherence in HIV care through nutritional support and counselling.

Many participants indicated that the nutritional support especially, and the nutritional program in general, helped them to take their ART medication properly, because some of them believed that ART needed special food. A male on ART and nutritional support user said:

I like it [the nutritional support]. If I am leaving for work early in the morning, I take my medication with me and since the medication is not good to take on empty stomach, I take the Plumpynut first. It is equivalent to one full Injera (Ethiopian local meal). If I take this, I am fine with my gastric upset (Adult male, age 54).

Because the nutritional support is ready to use with no need for further cooking it is especially convenient to take before ART medication. For others, it was a good substitute when other food was not available at home, as highlighted by a female participant.

I can say it is good and helpful even if I didn't get homemade foods, I take my ART medication after I take the Plumpynut because I believe that it is a good support (Adult female, age 29_15).

5.9 Summary of findings

This section has presented the barriers to and facilitators of utilisation of the nutritional program in HIV care. A summary of the main points of the barriers and facilitators is presented below.

Not eating well because of the loss of appetite and lack of access to adequate food were identified as dietary reasons for weight loss, while ART medication, HIV illness and opportunistic infections, alcohol and smoking addictions were labelled as perceived non-dietary reasons for weight loss. To this end, weight loss was the leading motivation for adults and caregivers to enrol in the nutritional program, followed by recommendations from health providers and absence of adequate food in the household.

Programmatic issues such as experiences of the nutritional support, nutritional counselling and health services emerged as crucial themes influencing utilisation of the nutritional program. When using the nutritional support, many participants boiled it or mixed it with other foods and water to improve appetite and minimise its assumed side effects. These included discomfort, stomach upsets, gastritis, nausea and vomiting and were barriers to utilisation. The ration size of the nutritional support distributed to participants was deemed to be adequate by many participants. However, sharing the nutritional support was widely practiced among participants while selling was widely reported by health providers. Selling was more common among adult participants, while sharing was a common practice among caregivers and female adults. Lack of understanding of the nutritional program, poverty and poor livelihood, and food insecurity contributed to selling and sharing of the nutritional support. In addition, the nutritional support was seen to make patients more vulnerable to stigma and discrimination, which in turn was a barrier to utilisation of the nutritional program.

The nutritional counselling component of the program was important but it had various constraints. It broadly involved counselling about the nutritional support, dietary practices, hygiene and sanitation but its focus, emphasis and extent varied. Nutritional counselling in the HIV care service mainly focused on the benefits and methods of use of the nutritional support and was largely given at the beginning as a one-off event. People accepted the nutritional counselling that was provided, but lack of household socioeconomic status threatened its applicability, while further challenges arose from its lack of comprehensiveness, uniformity and consistency.

Participants' experiences with health services was another programmatic issue that emerged from the analysis. Many of the health service issues, such as positive experiences in the nutritional care program, good patient—provider relationships, service strategies used to improve adherence, and quality indicators such as short waiting times enhanced utilisation of the nutritional program. Other issues of service and programmatic interaction and poorly skilled health providers were identified as barriers to nutritional program utilisation. In addition, a reduction in HIV care services in general and the nutritional program in particular constrained program utilisation. Previous enrolment in the nutritional program facilitated utilisation by improving knowledge and understanding about it.

Physical access to the nutritional program and program management and implementation were broader health system issues which emerged to influence utilisation of the nutritional program in HIV care. Increased frequency of visits to the health facility, movement of people to other places, unreliable and unaffordable transportation and reduction of nutritional program service sites were barriers that limited access to the nutritional program. In addition, funding issues such as inadequacy of funding and interruption in supply of the nutritional support were constraining utilisation.

Furthermore, the nutritional program was also criticised for the short duration of enrolment which was less than the time required for patients to achieve nutritional recovery. Lack of regular monitoring and follow up and problems with program integration directly or indirectly contributed to the challenges facing the nutritional program. The limited scope of the program only to the index patient (undernourished person living with HIV), limited follow up time after graduation, and issues of sustainability were also identified as challenges to utilisation. The size and training of the workforce delivering the nutritional program were inadequate and adversely influenced nutritional counselling, patient assessment, monitoring and follow up.

Socioeconomic and cultural factors, such as poverty and poor livelihood, the cultural meaning of food, religious and cultural issues, stigma and discrimination, distance and transportation and their cost, were major socioeconomic factors affecting utilisation of the nutritional program. Poverty and poor livelihood contributed to food insecurity and led to sharing and selling of the nutritional support while prolonging nutritional recovery and enhancing default. Furthermore, household food insecurity was a common scenario among study participants which in turn led to sharing of the nutritional support.

The cultural meanings attached to the nutritional support were a concern particularly among adults and inhibited the consumption of nutritional support by them, but not by children. In addition, religious fasting contributed to default and non-response because participants left the program during fasting periods. However, the influence of religious fasting on the utilisation of the nutritional program was less for children who did not have the same religious responsibilities.

Disclosure of positive HIV status varied by the target of disclosure (the person who knew the positive HIV status of the individual). While many disclosed their positive HIV status to their families, disclosure beyond the family was worrisome. Non-disclosure of positive HIV status was one barrier identified, because many were reluctant to use the nutritional program because of their fear of accidental status disclosure and associated stigma and discrimination. Participants feared that increased frequency of visits to the health facility or the public consumption, transportation and disposal of the nutritional support itself could reveal their HIV status to other community members. Participants were worried that this disclosure would lead to loss of rental homes, denial of access to house utilities such as toilets and bathrooms, loss of friends, friendship and networking and denial of children playing together.

The following chapter reflects on both the quantitative and qualitative findings in light of the literature to discuss and interpret the key issues for nutritional programs in HIV care setting.

CHAPTER 6: DISCUSSION

Introduction

This PhD thesis sought to examine the challenges faced by nutritional programs in HIV care in Ethiopia. The study examined the nutritional determinants and outcomes for adults and children living with HIV enrolled in the nutritional program in Ethiopia. Additionally, it explored the perspectives of program users (adults and caregivers of children living with HIV) and program staff (health providers and program managers) about factors enabling or constraining program utilisation.

This chapter firstly discusses the findings of the current study about how successful the nutritional program in Ethiopia is, compared with nutritional programs in other countries mainly in sub-Saharan Africa. In the second section, the demographic and socioeconomic, immunological and clinical, nutritional and anthropometric determinants of the nutritional outcomes are discussed and interpreted. In the third section, the barriers to and facilitators of utilisation of the nutritional program are further explored, including patients' knowledge and understanding about nutrition and the nutritional program, program-related factors, health system issues and sociocultural factors. In the fourth section, findings of the current study are conceptualised in light of the socioecological model supplemented by social determinants of health model to further understand the interactions between various factors affecting nutritional programs in HIV care. Finally, the strengths and limitations of this study are discussed in detail.

6.1 How successful has the nutritional program been

Nutritional programs in HIV care for adults and children have been modelled on nutritional programs developed for HIV negative children aged under five years (Food and Nutrition Technical Assistance (FANTA) 2004), where program effectiveness is defined as a recovery rate of greater than 75%, incompleteness of less than 15%, and death rate of no more than 10% (Carlos Navarro et al. 2015). However, the Ethiopian guideline regarding nutritional wellbeing among people living with HIV does not identify measurable targets or indicators to show how much change is expected to be achieved by the nutritional program (Federal Ministry of Health of Ethiopia 2008b). This lack of clarity about intended effects of the program on target populations or end results of the program makes it difficult to assess nutritional program effectiveness and creates problems of program monitoring and evaluation in Ethiopia.

Evidence from the current study demonstrated that half of adults and nearly three-quarters of children achieved nutritional recovery as a result of participation in the nutritional program. These findings were similar to previous studies that reported comparable magnitudes of nutritional recovery. For instance, a study in sub-Saharan Africa (Kenya and Uganda) reported that 47% of adults achieved nutritional recovery (Ahoua et al. 2011). Another study conducted in South Africa that used a different nutritional support (instant enriched maize meal) showed a similar finding, where approximately half the adults living with HIV enrolled in a nutritional program gained weight (Lategan, Steenkamp and Joubert 2010). On the other hand, another study conducted in a similar program but in a different context found only a 33% recovery rate among adults living with HIV (Sadler et al. 2012).

Program failure involves program incompleteness, non-response, relapse of undernutrition after recovery, and mortality while in the program. Program incompleteness was one of the components of program failure examined in this study, which found that 19% of adults and 14% of children did not complete the nutritional program. A similar level (23%) of program incompleteness in a nutritional program in adults was reported in a study conducted in Kenya and Uganda (Ahoua et al. 2011) while another study from Ethiopia reported higher (30%) program incompleteness (Kebede and Haidar 2014). Another study conducted in Ethiopia found a much higher program incompleteness (approximately 71%) among adults living with HIV enrolled in a nutritional program (Sadler et al. 2012). However, this study was conducted in the early stages of the nutritional program, where patients and health providers had minimal understanding about the nutritional program, which may have contributed to the higher magnitude of program incompleteness. In addition, the current study and the study by Sadler et al. (2012) were conducted in geographically different areas, which may also explain the difference in magnitude of program incompleteness.

In the current study, program incompleteness in children living with HIV was lower than in similar studies (Bahwere et al. 2008; Cames et al. 2016). For instance, Cames et al. (2016) indicated that 21% of HIV positive children enrolled in a nutritional program failed to complete the program in Senegal. In addition, in community based therapeutic care in Malawi, 27% of children did not complete the nutritional program (Bahwere et al. 2008). These variations in program incompleteness rates may be due to various reasons, such as differences in enrolment criteria, type of nutritional support used in the nutritional program and contextual differences. The magnitude of program incompleteness in the current study was lower in children than adults, which may be due to the small number of child participants in the current study.

There were also differences in the magnitude of non-response to the nutritional program between the current study and other studies. Non-response rates in both groups in this study were smaller (21% in adults and 14% in children) than in another study conducted in Ethiopia, which reported a 58% non-response rate among adult participants (Sadler et al. 2012) (children were not included in the study). Furthermore, a study from South Africa reported a similarly high rate (40%) for adults who did not improve their weight after four months of enrolment in a nutritional program (Lategan, Steenkamp and Joubert 2010). However, there were some potential methodological and programatic differences in these studies that might explain the differences in the findings. Nonresponse in the study by Sadler et al. (2012) was high, but the evaluation was conducted at the initial stages of the program implementation as a pilot study which might have led to high nonresponse rate because of implementation challenges. For instance, poor understanding of the program among both health providers and patients during the initial phase of the program implementation may have contributed to high non-response rates. The higher non-response rate in the study by Lategan, Steenkamp and Joubert (2010) may be partly due to limited resources and poor supply of the nutritional support used in the program which was worse than in the current study.

In the current study, the death rate among those on the nutritional program was estimated to be 2% for adults and <1% for children living with HIV, which was lower than the death rate of 12% reported by Ahoua et al. (2011) in Kenya and Uganda. In Malawi, Bahwere et al. (2011) reported a much higher death rate (38.5%) among adults living with HIV on a nutritional intervention. The big difference in death rates among adults between the current study and other studies might be due to the small number of hospitals involved in the current study influencing the total death rate or differences in program and country context. Furthermore, the death rates in the current study may be underestimated because of data loss, as described below in the limitations of this study (sub-section 6.5.2).

The other nutritional outcome examined in the current study was relapse of undernutrition after nutritional recovery. Findings of this study revealed that 18% of adults living with HIV had relapsed at least once after nutritional recovery and 27% of them had relapsed twice or more. Looking at children, 7% of them had relapsed at least once after nutritional recovery. Comparing the two groups of participants (adults and children), more adults relapsed than children, however, the sample size in children was small which might partly explain the difference in the magnitude of relapse. Nevertheless, relapse was a common phenomenon in many nutritional programs. A study conducted in Ethiopia found a comparable magnitude (20%) of relapse after nutritional recovery among adults living with HIV (Sadler et al. 2012). Additionally, another study from Kenya reported relapse of undernutrition, albeit a relatively low rate (10%), after nutritional recovery in adults (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009).

There were no other studies reporting relapse rates in HIV positive children to compare with the current study, which reported 7% relapse. This highlights that relapse of undernutrition among children living with HIV was not a major concern in nutritional programs, or that the magnitude of relapse might be equivalent to that seen in children who were HIV negative. For instance, a study of HIV negative children reported that 15% of them relapsed after nutritional recovery (Somassè et al. 2016). Furthermore, similar studies in HIV negative children demonstrated relapse of undernutrition as a critical challenge in nutritional programs targeting HIV negative children aged under five (Chang et al. 2013; Isanaka et al. 2009).

Compared with other studies, findings of the current study highlighted that the nutritional program had an equivalent or a better performance in relation to program outcomes. Qualitative findings in this study also demonstrated the importance of the nutritional program for improving weight, appetite and overall wellbeing. Many adults and caregivers acknowledged the changes to their nutritional wellbeing gained after enrolment in the nutritional program. Relapse of undernutrition after nutritional recovery might indicate the program's failure to address broader issues such as food insecurity and poverty among people living with HIV. Despite the relative success of the nutritional program in the current study, it falls far behind ensuring the nutritional wellbeing of people living with HIV. In the next section, the factors that challenged the nutritional program's effectiveness are discussed.

6.2 Determinants of nutritional program outcomes

The current study examined the factors that predicted program outcomes, including individual demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics.

6.2.1 Demographic and socioeconomic determinants

In the analysis, a number of demographic and socioeconomic factors were associated with the nutritional outcomes of the program.

Being an urban resident was associated with non-response and incompleteness of the nutritional program in adults living with HIV, but place of residence was not related to relapse of undernutrition. It is difficult to explain these associations given that living in urban areas generally means better availability of health services including the nutritional program. Additionally, investigation into factors that could lead to these outcomes (non-response and incompleteness) was beyond the scope of the current study. However, it can be speculated that non-response may be related to food insecurity and urban poverty and the resultant sharing and selling of the nutritional support, although the extent of sharing and selling in the program generally and with respect to urban–rural difference is not known. According to the WHO Commission on Social Determinants of Health (2008), people in urban areas in general live in extreme poverty which might possibly be helpful to explain the ineffectiveness of the nutritional program in urban areas.

The current study found that while lower levels of education attainment (primary and secondary education) did not predict program non-response or program incompleteness, they were significantly associated with relapses of undernutrition. It is speculated that better educational status was associated with better understanding about how to implement the learnings from the program once participants had graduated from it, particularly that they needed to maintain their weight and how to do this. Their higher educational status may also imply that they had higher incomes which may have contributed to improved food security and lower rates of relapse among those with higher educational attainment. It is interesting that educational attainment was not associated with other program outcomes given education might be expected to predict, for example, program adherence, as seen in a study conducted in Ethiopia (Kebede and Haidar 2014).

Findings of the current study found that employed people were more likely not to complete the nutritional program and to experience relapse of undernutrition more than once compared with those who were unemployed, but employment status was not related to nutritional program non-response. In terms of program incompleteness, it is possible that workers' schedules prevented them from attending the required appointments. The inverse relationship between employment and relapse was surprising because logic suggests that being employed would mean a higher income (Ongondi, Ayodo and Adoka 2016) and a higher likelihood of better food security. Given that our qualitative study did not further illuminate this, and we were unable to find evidence from previous studies demonstrating an inverse relationship between employment status and nutritional outcomes, further studies are required to explore this finding.

Although older age has been associated with nutritional program incompleteness in adults in other settings (<u>Huis in 't Veld et al. 2010</u>), age (adults or children) was not related to either program incompleteness or non-response in the current study. However, the qualitative inquiry component of the current study highlighted that older people may be more reluctant to use the nutritional support because of suspicions related to the cultural meaning of the nutritional support and religious fasting. Stronger religious beliefs and unacceptability of nutritional support's taste among older adults, as found in the qualitative study, to some extent might explain higher rates of incompleteness among them.

Findings of this study highlighted that not being a member of a community HIV support group was related to relapse of undernutrition, but not to program incompleteness or non-response. No other study has specifically examined the role of membership of community HIV support groups in relapse of undernutrition, but a systematic review that synthesised the role of community support groups in ART treatment reported that community HIV support groups were crucial in empowering people living with HIV to use services and also provided psychosocial support (Wouters et al. 2012). Another study conducted in sub-Saharan Africa among people living with HIV also confirmed that community-based HIV support services such as psychosocial and physical care and support improved CD4 count and adherence to ART (Kabore et al. 2010). It might be that community support groups are particularly important once programs are completed in assisting people to maintain weight beyond the support of nutrition programs through providing social networks, support and nutritional counselling (Campbell et al. 2013; Kreuter and Lezin 2002).

Gender was important in a study in Kenya and Uganda that indicated that females were more likely to recover from a nutritional program than males (Ahoua et al. 2011), but the current study did not find any association between gender and program incompleteness, non-response or relapse of undernutrition. The qualitative findings in the current study suggested that sharing the nutritional support was common among females and this has also been found previously (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009). These findings may be related to cultural practices where females are caretakers of the entire family and may share the food supplement as part of caring and because of cultural sharing practices, but these practices might inadvertently lead to an overall reduced effectiveness of the nutritional program in HIV care settings. Another study from Ethiopia also highlighted that sharing nutritional support was a crucial contributor to nutritional program non-response, but it did not indicate differences in sharing between women and men (Sadler et al. 2012). Hence, despite the absence of a statistical relationship between gender and nutritional outcomes, gender could be an important consideration during program planning and implementation because of women's role and position within the family and sharing practices related to this. Sharing practice and the drivers of sharing are further discussed below in subsection 6.3.2.

No demographic and socioeconomic characteristics predicted nutritional program outcomes in children living with HIV in the current study, possibly because of the small number of children involved. In addition, no previous studies have demonstrated the determinants of nutritional outcomes in children. Further research with a larger sample of children is warranted.

6.2.2 Immunological and clinical determinants

A range of immunological and clinical characteristics were evaluated and examined as determinants of the nutritional outcomes but only a few characteristics including WHO clinical stage, baseline functional status and being on ART for more than 24 months predicted nutritional outcomes.

WHO clinical stage is an important clinical indicator of the severity of HIV as well as being a mortality predictor (Bong et al. 2007; Zachariah et al. 2006). WHO clinical staging of HIV has four stages (Stages I–IV) where Stage I indicates the early stage of HIV infection and Stage IV indicates advanced HIV condition (WHO 2007). In addition, functional status is another measure of the clinical severity of HIV and is labelled as 'bedridden', indicating severe clinical condition, ambulatory indicating presence of mild to moderate clinical conditions and 'working' to indicate an apparently healthy situation (Justice et al. 1996).

In the current study, participants who were in WHO clinical stages II and III had a higher chance of program incompleteness than those in WHO clinical stage I, but there was no association between functional status and program incompleteness in adults. Neither WHO clinical stage nor functional status predicted relapse of undernutrition. Qualitative findings of this study indicated that some adults and caregivers were unable to travel to the nutritional service area because of their ailing health and the centralization of nutritional services, led them to miss their appointment dates. This may be an explanation for the relationship between severe WHO clinical stage and functional status and nutritional program incompleteness. A similar study in Ethiopia found that lower CD4 counts, another measure of clinical severity of HIV illness, were associated with program non-response (Sadler et al. 2012) but these researchers did not examine the role of WHO clinical stage and functional status on nutritional outcomes. Therefore, nutritional programs in HIV care should offer close monitoring and follow up of individuals with the most severe clinical conditions, while clinical assessment and management of infection should be incorporated into all nutritional programs.

It is well known that an advanced clinical stage of HIV indicates presence of and vulnerability to various clinical illnesses such as infection, which usually contribute to non-response (WHO 2007). The findings of the current study revealed the contrary, with those in the most advanced WHO clinical stage (Stage IV) demonstrating a lower chance of being non-respondent. As in the case of WHO clinical stages, findings of this study showed that adults living with HIV who were bedridden (worst clinical condition) were less likely to be non-respondent than those who were working or apparently healthy. It is plausible to hypothesise that, compared with participants who were not critically ill, those with advanced WHO clinical stage and bedridden functional status would visit health facilities more frequently and in so doing benefit from the close clinical monitoring of their HIV condition. However, this study was unable to provide further insight about the mechanisms under which those with severe clinical conditions responded to the nutritional program and this topic is recommended as an area of further studies.

In the current study and in a study from Kenya and Uganda (Ahoua et al. 2011), the presence of opportunistic infections was related to relapse of undernutrition but did not predict program incompleteness or non-response in adults. On the other hand, a study from Malawi with a non-randomised, uncontrolled intervention, a superior design to control for bias, found that the presence of opportunistic infections was a risk factor for nutritional program failure (Bahwere et al. 2011). As such, it is reasonable to postulate that the presence of opportunistic infections may contribute to nutritional program non-response because of clinical effects of illnesses. Despite the absence of a statistical association in this study and that of Ahoua et al. (2011), it is reasonable to suggest that to improve nutritional outcomes and wellbeing of people living with HIV, the presence of opportunistic infections should be given important consideration when planning and implementing nutritional programs in HIV care settings.

Unlike studies conducted in Ethiopia and Kenya where being on pre-ART or not having started ART were associated with nutritional program non-response and incompleteness (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009; Sadler et al. 2012), the current study did not demonstrate this relationship. Similarly, in another study conducted in (Kenya and Uganda), being on pre-ART placed people at increased risk of program failure (non-response and program incompleteness) (Ahoua et al. 2011). Bahwere et al. (2011) found that being on pre-ART was related to nutritional intervention failure (mainly non-response) and being on ART therapy improved response to treatment and nutritional status. Hence, before enrolling individuals who have not started ART in nutritional programs, HIV care providers should pay special attention to engaging them in the care. However, after data collection for the current study, new protocols were developed and changes made in testing and treatment approaches in HIV care. The new protocols dictate that after testing positive for HIV, individuals must be enrolled in ART care immediately (Nash, Yotebieng and Sohn 2018; Yotebieng et al. 2019). In this regard, the above recommendation regarding pre-ART might be applicable to those who are at the initial stages of ART initiation and who meet enrolment eligibility for nutritional programs. Although we were unable to find studies that examined the association between duration on ART and relapse of undernutrition, the findings of this study indicated that adults living with HIV who were on ART for more than 24 months were more likely to relapse than those who had been on ART for less than six months.

6.2.3 Nutritional and anthropometric determinants

The impact of nutritional and anthropometric characteristics of adults and children living with HIV on their outcomes in the program were examined in the current study. Findings highlighted that severe acute undernutrition at enrolment was associated with nutritional program non-response in adults only, and incompleteness in adults and children living with HIV. Similar observations have been made elsewhere, for instance in Ethiopia (Sadler et al. 2012) and other countries in sub-Saharan Africa (Ahoua et al. 2011; Lategan, Steenkamp and Joubert 2010), where severe acute undernutrition at enrolment was associated with nutritional program failure, i.e. incompleteness and non-response, among adults living with HIV.

Anaemia among people living with HIV is common (<u>Gedefaw et al. 2013</u>; <u>Jaganath et al. 2014</u>) but to our knowledge there have been no studies examining the impact of anaemia on nutritional outcomes in HIV care. Findings in the current study highlighted that in adults, being anaemic at enrolment in the nutritional program was associated with program incompleteness but not with non-response. It is possible that the presence of anaemia is an indication of severe undernutrition that negatively affects the nutritional outcomes.

Generally, the findings of the current study supported existing evidence where poorer nutritional status at enrolment was consistently associated with incompleteness and non-response to nutritional programs in HIV care settings. It is also possible that the severity of the HIV condition and a short enrolment period would be the likely explanation for the relationship between poorest nutritional status and nutritional program outcomes. For instance, our qualitative study findings suggested that the recommended enrolment period for severe acute undernutrition (usually six months) was not long enough to achieve the required level of weight gain given the severity of undernutrition and other infections. Similarly, another study from Kenya reported short duration of the nutritional program in an HIV care service (Ongondi, Ayodo and Adoka 2016). Given this evidence, it is reasonable to suggest that, nutritional programs in HIV care should therefore take into account those with severe acute undernutrition at enrolment and consider a longer enrolment duration as vitally important to prevent the poor outcomes identified in this and other study findings.

6.3 Barriers to and facilitators of nutritional program utilisation

The barriers to and facilitators of nutritional program utilisation identified in this study involved knowledge and understanding of adults and caregivers about nutrition and the nutritional program, program-related issues, health service, health system, and sociocultural factors. These are discussed in turn below. In addition, the interrelationships between the different factors and their implications for the nutritional program in HIV care are discussed and compared with other studies.

6.3.1 Patients' knowledge and understanding of the nutritional program

Knowledge and understanding about the causes of undernutrition among people living with HIV and enrolled in the nutritional program were found to be important facilitators. In addition, motivation for enrollment and continuous utilisation of the nutritional program is discussed below.

Knowledge of causes of undernutrition and motivations for enrolment

The current study highlighted variations in perceived reasons for weight loss. Some participants related their weight loss to food and nutrition factors such as lack of appetite and inadequate access to food. This demonstrated an acceptable level of knowledge of causes of undernutrition among people living with HIV, which is consistent with the biomedical explanations of undernutrition (Mangili et al. 2006). Despite differences in contexts, a study conducted in India also reported that people living with HIV had moderate knowledge of nutrition and the need for improved nutrition during HIV illness (Anand and Puri 2013).

A study conducted in Ethiopia indicated that an individual's initial motivation, particularly the perception that nutritional supports would fill their dietary gaps, was crucial for enrolment in the nutritional program to achieve a favourable nutritional outcome (Olsen et al. 2013). Motivation for enrolment was mixed in the current study. Some issues mentioned as motivators for enrolment, such as weight loss and recommendations of health providers, were consistent with the enrolment criteria or aims of the nutritional program. On the other hand, motivators such as lack of appetite and absence of adequate food in the household were beyond the scope of the nutritional program. McDermott et al. (2003) also demonstrated variations in motivation for enrolment in a nutritional program, affecting continuous utilisation and nutritional outcomes, despite the big difference in context with the current study.

Perceived severity of the illness has been highlighted as important in enhancing healthy behaviour because it is based on the individual's evaluation of the consequences that the condition would have on their life (Becker 1974). In the current study, the severity of weight loss and an understanding of the benefits that the nutritional program could have on their life may have encouraged participants to enrol in the nutritional program. Thus, at an individual level, good knowledge about undernutrition and motivations that align with the enrolment criteria of the nutritional program could act as facilitators of program utilisation. On the other hand, and as demonstrated elsewhere in this thesis, poor livelihoods, poverty and food insecurity were entrenched features of these individuals' lives. It is therefore possible that household food insecurity and poverty had motivated individuals to enrol in the nutritional program, as some participants themselves highlighted. However, addressing poverty and food insecurity was not part of the aim of the nutritional program in HIV care settings in Ethiopia. This may need to be addressed at a broader policy level to sustain desirable nutritional outcomes among those living with HIV in this nation.

Understanding about the program and motivation for ongoing utilisation

As findings of this study highlighted, there was poor understanding about the nutritional program. Adults and caregivers were mainly aware of the nutritional support or Plumpynut, with little mention of counselling and other components of the nutritional program such as nutritional assessment. These findings support a previous study from Ethiopia which also found that participants' understanding of the nutritional program was limited to the nutritional support (Hussien et al. 2015). Poor knowledge about the nutritional program might lead adults and caregivers to share or sell the nutritional support in exchange for other household consumables. In the current study, the nutritional support was considered as a food that could be shared among families or sold to exchange for other needs of the household, as a health provider highlighted. It can be speculated that various factors such as limitations in nutritional counselling, poverty and poor livelihood contributed to poor understanding of the nutritional program and drivers for poor adherence. This may also relate to the low level of education as 30% of adult participants in the quantitative study and 33% of those in the qualitative interviews had not received any formal education.

The current study also examined the reasons for ongoing utilisation. The perception that the nutritional support is better in nutritional value than other foods, concern about weight loss and positive experiences with the health service were the main reasons for ongoing utilisation. Some participants believed that the nutritional support was an important food especially designed for people living with HIV that complemented ART and other medications. In addition, because of its salty taste, the nutritional support improved water consumption by some participants in this study, while some participants believed that drinking more water may reduce the toxicity of ART medication. A similar study into the acceptability of nutritional support in HIV care settings in Ethiopia highlighted how perceptions that the nutritional support protected individuals from adverse effects of ART motivated utilisation (Olsen et al. 2013). Despite the importance of such beliefs and experiences in enhancing continued use of the nutritional program, many did not like the taste of the nutritional support.

Weight loss was also reported to be a source of both initial and ongoing motivation to participate in the nutritional program, findings consistent with the program's aim and enrolment criteria. In addition, once started on the nutritional program, adults and caregivers realised improvements in appetite, weight and overall health and this helped participants remain with the program. These findings were in agreement with studies conducted in Ethiopia (Kebede and Haidar 2014; Olsen et al. 2013) and Kenya (Ongondi, Ayodo and Adoka 2016) that identified improved weight, health and return to work as important reasons for continued utilisation of nutritional programs. Such experiences may be helpful to improve utilisation of the nutritional program by providing demonstrable experiences about its benefits.

The prior experience of adults and caregivers with the nutritional program played an important role in their continued utilisation of the program. Prior experience in the nutritional program might have allowed individuals to acquire adequate knowledge about the nutritional program and its role in improving weight and nutritional status. However, the fact that some participants had prior experience of the program suggested they had multiple enrolments in it. This is not in the program's interest and might indicate dependency among participants and/or a failure of the program to prevent relapse. No other studies have examined how prior experience influenced ongoing utilisation of a nutritional program. Other factors such as HIV community support and nutritional counselling were important motivations behind ongoing utilisation of the nutritional program elsewhere (Kebede and Haidar 2014) but such factors were not displayed in the current study.

Good knowledge of nutrition, alignment of the motivations for enrolment to the nutritional program and factors which enhance ongoing motivation such as improved weight and health status were identified as facilitators of utilisation. Other factors such as poor understanding about the nutritional program were barriers to program utilisation.

6.3.2 Program related barriers and enablers

Program related factors identified as affecting use and outcomes included issues with nutritional counselling, the nutritional support used in the nutritional program, health service factors and previous enrolment in the nutritional program, as discussed below.

Nutritional counselling

Despite the fact that nutritional counselling was stipulated in the Ethiopian national nutritional program(Government of the Federal Democratic Republic of Ethiopia 2013–2015), findings of this study indicated that nutritional programs in HIV care settings lacked comprehensiveness, structure, consistency, goal oriented counselling guidelines and regular training of health providers during implementation, highlighting a policy–practice gap. Overall, nutritional counselling was found to be an enabling factor for utilisation of nutritional program by providing information about the nutritional support, mechanisms of use and its benefits. Receiving even one session of nutritional counselling benefited adults and caregivers by providing them with opportunities to discuss personal issues. The findings of the current study were consistent with another study which indicated that nutritional education on the benefits and purpose of nutritional support was fundamental for better utilisation of the program (Frank et al. 2013). Many other studies have reiterated the effectiveness of nutritional counselling in improving the nutritional wellbeing of people living with HIV (Alo, Ogbonnaya and Azuogu 2014; Gaikwad et al. 2013). There was, however, little evidence about the experiences, practice and application of nutritional counselling in a specific nutritional program in HIV care settings.

Findings of this study highlighted that nutritional counselling in the HIV care setting was affected by challenges that in turn influenced program effectiveness and success as a whole. These challenges included its medicalised orientation and narrow focus, absence of continuity, lack of comprehensiveness and its unstructured delivery. Medicalisation refers to a focus on the nutritional issues being considered only as medical problems that could be addressed by treating undernutrition (Gitome et al. 2014; Greenaway 2009). The medicalised orientation of nutritional counselling may have contributed to its lack of comprehensive and holistic content. This may have affected utilisation and maintenance of weight after nutritional recovery, because study participants lacked broader dietary knowledge. For example, a study conducted by Kuria (2010) in Kenya demonstrated that education about foods that were suitable for health and nutritional wellbeing was not given enough emphasis during counselling of people living with HIV. Hence, program planners should consider re-orientation of the nutritional counselling to make it more comprehensive so as to enhance effectiveness of nutritional programs in HIV care.

The medicalised orientation of the nutritional counselling also contributed to concerns related to the session duration, content, applicability and acceptability of it in HIV care. In the current study, nutritional counselling did not usually occur regularly throughout the program but was generally provided on a once-only basis. As a result, health providers mainly focused on the immediate medical needs of clients rather than embracing a comprehensive approach to counselling. This is reflected in the broader literature on the time limits for preventative approaches. For example, a study from Kenya reported poor health conditions as a barrier to nutritional counselling because the time set aside for counselling was needed instead to provide medical care to the individual (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009). Another study conducted on estimated time spent on primary care services by primary care physicians indicated shorter times allocated for preventive services including nutritional counselling (Pollak et al. 2008). In a study conducted in Canada that examined the status of nutritional counselling in a general health care setting, lack of time and compensation for health providers also emerged as barriers to providing proper nutritional counselling (Wynn et al. 2010), showing that the problem is widespread even despite contextual differences between Ethiopia and Canada. In addition to the frequency and continuity of counselling sessions, the short duration of the counselling session was noted as a factor hindering its effectiveness in the current study.

Another challenge to nutritional counselling in this study was the content. According to participants, nutritional counselling had a key focus on the nutritional support, with brief or no coverage of dietary practice, hygiene and sanitation issues. This may be because health providers focused on the immediate clinical needs. Similarly, another study in Ethiopia reported limited and unsatisfactory content in the nutritional counselling component of the nutritional program (Hussien et al. 2015). The narrow focus of nutritional counselling on the nutritional support contributes to the problems of understanding about the nutritional program in HIV care, where participants considered the nutritional program as comprising the nutritional support only. This has important implications for the risk of relapse once leaving the program and the supply of nutritional support has ceased.

Maertens (2011) has argued that an individual's understanding and acceptance of a counselling or education program is a precursor for its applicability in HIV care settings. Even though the nutritional counselling was mainly about the nutritional support, sound acceptability of it by participants was demonstrated in the current study. However, concerns about the applicability of the nutritional counselling was mentioned by health providers. Another study conducted in Ethiopia reported that the nutritional counselling was not as helpful as expected, implying there were issues with its acceptability and applicability (Hussien et al. 2015). One factor that contributed to the problems of applicability of the nutritional support was the lack of consideration of participants' socioeconomic conditions in the nutritional counselling, where little attention was paid to the social, cultural and living conditions within which HIV patients live.

The absence of working and training guidelines for nutritional counselling were additional identified inadequacies, which probably contributed to the lack of consistency of content and quality among health providers. Similar problems in relation to training were found by the study that explored barriers to nutritional counselling among people living with HIV in the US, despite the contextual difference in the study settings (Maertens 2011). The poor quality of counselling sessions may also have contributed to patients' misuse of the nutritional program, such as selling and sharing of the nutritional support.

In summary, the nutritional counselling facilitated utilisation of the nutritional program but was characterised by the lack of comprehensiveness and consistency, limited training of health providers and absence of counselling guidelines, which primarily relates to institutional and policy level factors. Policy implementation issues included lack of continuous training and absence of clear and defined counselling guidelines. Such institutional and policy challenges have an impact on individual level factors such as understanding, acceptability and applicability of the nutritional counselling, reinforcing the point that factors challenging the nutritional program are mutilifactorial. Furthermore, the medicalised orientation of the nutritional program was a fundamental problem leading to the lack of a holistic aproach in nutritional counselling, where major emphsis was given to treating undernutrition. Hence, addressing the institutional and policy level challenges in the nutritional counselling may help to improve the effectiveness of nutritional programs in HIV care through improvement in individual understanding and knowledge about nutrition in general and the nutritional program in particular.

Experience of the nutritional support

Issues related to the nutritional support presented an important challenge to the utilisation of the nutritional program. In this study, adults and caregivers had a positive view about the nutritional support provided in the nutritional program in HIV care. However, problems related to the method of use, taste, perceived side effects, stigma, selling and sharing constrained effective consumption of the nutritional support. These issues also contributed to program incompleteness or non-response to the nutritional program particularly among adult participants.

Mixing and cooking of the nutritional support may degrade the nutritional value of it and affect ration size. This in turn may reduce the efficacy of the nutritional program by delaying nutritional recovery. Despite the nutritional support being a ready to use food, participants stated they frequently mixed it with water, milk or other foods. This finding was in agreement with studies conducted in Kenya and Ethiopia that reported mixing of the nutritional support with local foods was a common practice (Dibari et al. 2012; Hussien et al. 2015). In the current study and the Kenyan study (Dibari et al. 2012), the reasons for mixing the nutritional support were to improve consumption (appetite) and to avoid diet boredom with it. Alleviating side effects was also reported as reason for mixing the nutritional support with other foods, a point also found in another study conducted in Ethiopia (Hussien et al. 2015). Furthermore, in the current study the practice of mixing was undertaken to minimize the frequency of visits to health facilities by increasing the ration's volume and using it for a longer period than for the prescribed duration.

Another issue found in other studies related to the nutritional support was the ration size of the nutritional support consumed, with a study in Kenya finding concerns that the ration size was too small, with a recommendation to increase rations (<u>Ongondi, Ayodo and Adoka 2016</u>). However, ration size was not raised as a concern in this study.

However, findings of the current study indicated that the duration of enrolment in the nutritional program, which usually ranged from three to six months, may be too short for some individuals with severe acute undernutrition. Hence, increasing the duration of enrolment in the nutritional program may benefit individuals living with HIV, particularly those with severe acute undernutrition and severe clinical conditions but further study into this is warranted. No other studies reported findings about program duration.

Taste and perceived side effects of the nutritional support (Plumpynut/Plumpysup) were also constraints to its utilisation. The reported side effects were upset stomachs and gastritis, nausea and vomiting and diarrhoea in adults and vomiting in children. Similar findings in Ethiopia were reported by Hussien et al. (2015) who stated that the nutritional support caused discomfort and temporary impairment of health. Participants in both studies claimed that the oily, salty and sugary character of the nutritional support was responsible for the perceived side effects (Hussien et al. 2015). In both studies, most side effects associated with the nutritional support were temporary, manageable and occurred at the beginning of enrolment in the nutritional program. However, such findings still highlight the importance of side effects because the first visit is the most important period, after which many participants may default, as found in the current study.

Issues related to the taste of the nutritional support were more pronounced in adults than children due to the salty (Plumpysup) and sugary (Plumpynut) taste in this study because children are not adapted to a specific food taste like adults. The taste may vary depending on the type of nutritional support used, but there were mixed findings from other studies in relation to this. In line with the findings of the current study, <u>Dibari et al. (2012)</u> in Kenya reported concerns with taste of the nutritional support. However, in another study in Kenya, taste was not a concern but the nutritional support used was fortified blended flour (<u>Ongondi, Ayodo and Adoka 2016</u>), which was different from Plumpynut/sup in terms of taste and palatability.

According to a study from Zambia, adults preferred less sweet and salty types of nutritional support (Catholic Relief Services 2011). However, Plumpynut/sup was originally designed to address undernutrition in children and is now used to address undernutrition in adults and children living with HIV (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009). Hence, the sugary and salty taste may be related to the lack of modification of the nutritional support to suit adult tastes and resemble local foods in texture. As findings of the current study and the above evidence indicated, the taste of the nutritional support used in HIV care could vary across cultures, contexts and the type of nutritional support used. Consequently, manufacturers of nutritional supports for nutritional programs should consider local taste and palatability to improve utilisation and effectiveness of nutritional programs in HIV care.

It was also found that a significant number of adults and caregivers shared the nutritional support with family members. This was particularly the case for female participants. Other studies have also found sharing practices among nutrition program participants (<u>Dibari et al. 2012</u>; <u>Hussien et al. 2015</u>; <u>Kebede and Haidar 2014</u>). For example, a qualitative study from Kenya found that half of participants reported sharing the nutritional support with other children and adults (<u>Dibari et al. 2012</u>). In addition, a study conducted in Ethiopia reported mothers participating in a nutritional program shared the nutritional supplement with their children (<u>Hussien et al. 2015</u>). A number of other studies have also found that women were more likely to share the nutritional support than men (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009; Sadler et al. 2012).

In this study, two broad factors contributed to the sharing practice. The first dimension was related to the individual level attributes such as the lack of understanding about the nutritional program and sharing attitude which was consistent with other studies from Ethiopia (Sadler et al. 2012) and Kenya (Dibari et al. 2012). The second dimension that enhanced sharing included social and cultural norms, food insecurity and poverty. A study from Zambia likewise found that sharing of nutritional support was driven by perceived social obligations to share food and food consumption norms (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009). Adults and caregivers also shared the nutritional support with others to fulfil household food requirements because of lack of adequate food, which was also found in another study done in Ethiopia (Sadler et al. 2012). Hansen et al. (2015) examined a therapeutic nutritional program among HIV positive women and highlighted the impact of household food insecurity on sharing. Sharing was also used as a mechanism to delay program exit so as to keep getting the food, which was consistent with a study from Kenya (Dibari et al. 2012). While one study from Ethiopia reported that a perception that the nutritional support was considered as medicine limited sharing (Olsen et al. 2013), this was not the case in the current study.

No adults or caregivers in the current study reported selling the nutritional support but participants spoke of the availability of it in the market. Similar findings were found in other studies conducted in Ethiopia (Hussien et al. 2015; Kebede and Haidar 2014) and elsewhere (Dibari et al. 2012). While adults and caregivers were reluctant to admit that they sold the nutritional support, health providers in this study reported that selling was a common practice, challenging the effectiveness of the nutritional program. They reported that adults and caregivers sold the nutritional support to purchase other household consumables for other family members, including children. The underlying issue contributing to selling was the interaction of individual level factors such as poor individual understanding and perception about the nutritional program and poor socioeconomic status, as discussed below.

6.3.3 Health service barriers and enablers

Participants highlighted a number of health service factors that affected utilisation of the nutritional program including health service location, the relationship between patients and health providers, and the service strategies employed to improve adherence to the nutritional program.

Health service location

The quantitative findings in the current study found that participants enrolled in Shul and Lemlem Karl hospitals were less likely to gain sufficient weight in the nutritional program after program completion (non-response) than those in Mekelle. The differences in incompleteness and non-response between hospitals in this study may be attributed to the relative remoteness of these two hospitals which could have negatively affected human resource allocation and supply distribution. Moreover, being located in a remote place may also contribute to problems of distributing the nutritional support, training of health providers, and monitoring and supervision. Levesque, Harris and Russell (2013) indicated the importance of geographic location of a health service for utilisation, where more remote health facilities can fall in short of important resources which in turn can influence utilisation and effectiveness of health programs. Ahoua et al. (2011) found similar differences in program failure (incompleteness, non-response and mortality) between program sites but did not report on the remoteness of the sites.

Another study conducted in Ethiopia reported a higher non-response rate among those who attended a hospital than a primary health centre (<u>Sadler et al. 2012</u>). However, because of feasibility issues, this study did not include primary health care centres and thus a comparison between hospital settings and primary health care centres was not possible. Comparison of the two settings would be useful in future research.

Trust and relationship with health providers

Trust and a positive relationship with health providers enhanced utilisation of the nutritional program in the current study. According to <u>Østergaard (2015,p1047)</u> "trust is a voluntary course of action, which involves the optimistic expectation that the trustee will do no harm to the trustor and is increasingly perceived as an important influence on health system functioning". <u>Østergaard (2015,p 1047)</u> indicated that "trust reduces the social complexity and inherent uneven distribution of power between clients and providers". Many studies have highlighted that trust between patients and health providers, and patients and the health system is crucial for the utilisation of the health service (<u>Meyer et al. 2008</u>; <u>Meyer and Ward 2008</u>; <u>Østergaard 2015</u>). In this study, the positive relationship and trust between health providers and patients in the health facility emerged as a crucial factor facilitating utilisation of the HIV service in general, and the nutritional program in particular.

Dawson-Rose et al. (2016) argued that because of the sensitivity and chronicity of HIV illness, trust and respectful care is crucial for the utilisation of services. Participants in the current study felt that health providers at Shul hospital provided particularly respectful care. Despite their distant location from the place where the health service was organised, Shul and Lemlem Karl hospitals were less complex in terms of organisation and client load than Mekelle hospital. This may have created an opportunity for health providers to spend more time building relationships with patients that enhanced trust among service users and providers. A similar study conducted in Ethiopia also indicated that clients preferred low-level health facilities such as primary health care centres (Balcha, Jeppsson and Bekele 2011) which are less complex and with lower caseloads than hospitals. As indicated above, this study did not include primary health centres but health facilities with smaller client loads may have better client—health provider relationships and trust, leading to better utilisation of the nutritional program. Despite the good patient—health provider relationship in the remote hospitals, being enrolled in these hospitals was associated with program incompleteness and non-response as indicated in the previous sub-section regarding location, which could be an area of further investigation.

Adherence to the nutritional program and strategies to improve adherence

There is no clear definition of adherence to the nutritional program but adherence is a broader concept than mere consumption of the nutritional support, and may encompass many issues such as missing appointment dates and not consuming the required rations. Kebede and Haidar (2014) used a self-report from study participants in an Ethiopian study using the Morisky 8-item measurement assessment scale (Tandon et al. 2015) to measure adherence. They reported a low level of adherence to the nutritional program (Kebede and Haidar 2014). The current study indicated that missing an appointment date and not consuming the required ration was common amongst participants.

Findings of this study highlighted that adherence to the nutritional program was influenced by various characteristics of participants. Elsewhere, those on ART adhered to the nutritional program better than those on pre-ART (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009). There may be two benefits of ART in improving adherence to the nutritional program. Firstly, the ART treatment can improve patients' clinical condition to the extent that they are able to attend the clinic. Secondly, being on ART allows people living with HIV to become more engaged in the nutritional program than those on pre-ART, and to benefit from activities such as adherence counselling and opportunities to engage in HIV community support groups. Those on pre-ART are only required to visit the health facility once every six months and hence have few opportunities for engagement.

There is no evidence that longer duration of enrolment in the nutritional program contributed to low adherence in the current study, but this may be an issue in areas where the nutritional program is geographically inaccessible and hence contribute to non-adherence and program incompleteness. Access to the nutritional program was an important issue in the current study which will be discussed below. In addition, absence of adequate and clear information about the nutritional support contributed to participants missing nutritional program appointment dates in the current study.

Comparing adults and children regarding adherence to the nutritional program, caregivers' reports showed that children adhered to the nutritional program better than adults. They were less concerned about the taste and fasting rules were less applicable to children. Various factors such fasting, stigma and discrimination which were less applicable to children were fundamental barriers to adherence for adults in this study, which will be discussed below. However, no external studies have compared levels of adherence to nutritional programs between adults and children.

According to the findings of this study, various mechanisms were used by health facilities to improve adherence of adults and caregivers to the nutritional program. These comprised monitoring changes in BMI, making clients return empty sachets to the health facility, home to home tracking of clients and peer education. However, it is difficult to determine whether these strategies led to improvements in adherence. Home to home client tracking is no longer in place because of its cost. There is no other evidence on the impact of client tracking in improving adherence to the nutritional program but client tracking using case managers to enhance adherence to ART was shown in many studies (Kunutsor et al. 2012; Thurman et al. 2010) which may also be a relevant strategy in the nutritional program. There is evidence showing the effectiveness of peer education in improving adherence to ART (Gusdal et al. 2011; Wouters et al. 2014) and this strategy may also be a way to improve adherence to the nutritional program in HIV care.

In summary, health service factors such as location, in terms of the HIV clinic in the health facility, and patients' trust of health providers facilitated utilisation, but the relative remoteness of the health facility was a barrier. Health facilities employed various measures to enhance adherence to the nutritional program but some of these depended on individual acceptability and applicability, and this needs further investigation. However, poor adherence to the nutritional program was attributed to various institutional and individual level factors while the measures used to improve adherence is primarily focused on individual level barriers.

Quality of service and utilisation of the nutritional program

There are various service quality indicators (<u>Abuosi and Atinga 2013</u>; <u>Øvretveit 2000</u>). For instance <u>Øvretveit (2000, p 75)</u> viewed quality of service as meeting patients' expectation through "giving patients what they want", and "giving them what they need" using reasonable resources in the shortest time possible. In the current study, human resource issues, service integration and waiting time in health facilities are discussed.

Service integration is a key issue in HIV services including the integration of the nutritional program (Fergusson and Tomkins 2009; Semba, De Pee and Bloem 2012) but poor integration of the nutritional program with other HIV services (mainly ART) was identified as a barrier to program utilisation in the current study. This finding was consistent with a study conducted in Ethiopia that revealed the lack of concordance between the nutritional program and other HIV services such as ART, where participants were required to visit a health facility more than once in a month for the nutritional program and ART (Hussien et al. 2015). Similarly, absence of integration (alignment) between appointment dates for the nutritional program and ART was a major concern in a study conducted in Kenya (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009). This study further demonstrated the lack of integration between nutritional and HIV services through the use of different registration books for the nutritional program and other HIV services. This had the potential to have an adverse effect on nutritional program utilisation by over-burdening health providers.

Another parameter of quality of service is waiting time, and while findings of a study in Kenya found waiting times constrained utilisation of the nutritional program (Food and Nutrition Technical Assistance II Project (FANTA-2) 2009), this was not identified as a major concern in the nutritional program in the current study. However, the study in Kenya was an initial evaluation at the beginning of program implementation and was conducted in an area with high client load. Waiting time might vary by context such as service areas, client load and other programmatic issues, and assessment of it should be examined over span of time rather than in a spot assessment. Hence, the finding of the current study might not be conclusive but it can serve as baseline evidence for a further study regarding waiting time as an important indicator for quality of service.

Findings of this study highlighted that an inadequate workforce in terms of numbers and quality was an important challenge in the nutritional program. Quality of health providers refers to their experience and skill and it was reported that some health providers lacked adequate training to assess, categorise, enrol and prescribe the nutritional support. Major inconsistencies were also reported in the monitoring and follow up of participants. This finding was consistent with another study conducted in Ethiopia, which found health workers' lack of clarity about the program and noncompliance with program protocols were significant contributors to nutritional program incompleteness (default) (Sadler et al. 2012). The study by Sadler et al. (2012) was conducted in a geographically different context from the current study and at the initial stages of the nutritional program, but issues related to health providers' skills and experience appear to have remained. Furthermore, a study from Kenya reported that issues of inappropriate staff training contributed to the quality of service in the nutritional program (Dibari et al. 2012).

Health providers and program managers interviewed in the present study suggested that the nutritional program in HIV care was not adequately staffed given the client load of the hospitals. Shortages of staff, working space and out-of-stock issues related to the nutritional program were also reported in other studies (Callaghan, Ford and Schneider 2010; Food and Nutrition Technical Assistance II Project (FANTA-2) 2009; Heller et al. 2000; Zachariah et al. 2009a). Thus, improving the numbers and quality of staff in the nutritional program in HIV care is important to improve effectiveness of the nutritional programs and maintain nutritional wellbeing of people living with HIV.

6.3.4 Health system barriers and enablers

The previous sub-section addressed health service issues that facilitated or constrained utilisation of the nutritional program. The following section discusses the broader health system challenges such as access, funding and NGO involvement, implementation and management of the nutritional program, and their influence on utilisation. Concerns were expressed about access, such as distance from health services (overlapping the issues outlined above), program funding and resource allocation in the nutritional program, sustainability, and supply of the nutritional support, all of which were crucial in influencing program utilisation. In addition, implementation issues such as technical difficulties were important health system factors that influenced utilisation of the nutritional program.

Access to the nutritional program

Access to the nutritional program was influenced by issues of physical access and funding. Levesque et al (2013), defined access to health care services as "resulting from the interaction of determinants pertaining to characteristics of individuals (e.g. the place where they live, their economic resources and their social status) and of services (e.g. quantity, location of facilities, costs)" (Levesque, Harris and Russell 2013, p 6). Dimensions of access include approachability, acceptability, availability and accommodation, affordability and appropriateness (Levesque, Harris and Russell 2013).

Findings of the current study highlighted that physical proximity to the nutritional program influenced users' access to it. Participants reported that distance and transport to services and associated costs created major barriers to program utilisation. Three factors exacerbated the access difficulties. First, some patients had to travel to other locations for temporary jobs where they could not access HIV services such as ART or the nutritional program. Second, the number of HIV care settings offering the nutritional program has been reduced since 2015, contributing to the challenges of physical accessibility. Thirdly, the nutritional support element of the program was more centralised than other ART services, which again made physical access difficult. Transporting the bulky monthly supply of rations of the nutritional support was described as difficult for ailing persons in the current study and in other studies in Ethiopia (Sadler et al. 2012) and Kenya (Dibari et al. 2012), which again was related to the physical inaccessibility of the nutritional program. In a study comparing acceptability of nutritional programs which used two ready to use nutritional supports in Vietnam, infrastructure issues were reported as a fundamental challenge (Frank et al. 2013). Poor infrastructure such as difficult roads is likely to affect access to the nutritional program because more than 80% of the Ethiopian population live in rural areas where there are no roads or other infrastructure. In Kenya, (Dibari et al. 2012) also demonstrated that access difficulties including distance challenged the nutritional program.

Funding, resource allocation and the nutritional program

Although there were no out-of-pocket-fees for patients in the nutritional program, the overall reduction in program funding and issues around supply limited access to services. The nutritional program is mainly reliant on donor funding and the nutritional support is currently manufactured in Ethiopia by a private firm while some ingredients such as milk are imported. Depending on the terms and conditions of the NGO, the nutritional support in HIV care in Ethiopia is purchased from the local firm or imported but there is no difference in brand, packaging or ingredients between the imported product and that manufactured in Ethiopia. A similar Ethiopian study that examined the same program but in a different setting reported that the nutritional programs were expensive and mainly dependent on external funding and importation of the nutritional support (Plumpynut/sup) (Sadler et al. 2012). This suggests that the funding and sourcing of the nutritional program in HIV care settings in Ethiopia lacks stability.

This study was unable to explore the budgets allocated to nutritional programs by NGOs, but the number of NGOs involved in the nutritional program has fallen since 2015. A decline in interest in the nutritional program among local and international NGOs has led to a reduction in the number of sites providing the nutritional service. According to a study conducted by Wamai (2009), 31% of the Ethiopian health system is financed by the government while donors organisations including NGOs (local and international) provide 37% of health system funding. A further 31% of funds come from out-of-pocket payments while the remaining 2% come from other private employees and funds. This demonstrates the strong dependence of the Ethiopian health system on NGOs. Funding constraints in nutritional programs in HIV care settings have also been reported in studies conducted in Uganda (Yager, Kadiyala and Weiser 2011) and Malawi (Manary, Ndekha and van Oosterhout 2010). The reliance on donor funding has led to funds being made available for short periods only, creating gaps in funding and technical support.

The role of NGOs in the implementation and sustainability of the nutritional program emerged as an important concept in this study. The contribution of NGOs to global health development and wellbeing is crucial, mainly in the areas of communicable and non-communicable diseases, HIV and nutritional disorders (Gellert 1996; Sulzbach, De and Wang 2011). Non-governmental organisations play a vital role in strengthening and supporting health systems to improve the accessibility and quality of health services in developing countries (Mussa et al. 2013; Sulzbach, De and Wang 2011). However, it has been argued that NGOs may contribute to the weakening of health systems because of excessive dependence on them for funding and expertise (Shandra, Shandra and London 2010).

Despite the vital contribution of NGOs to the Ethiopian health system, findings of this study indicated that the phasing out of support by some NGOs has weakened the nutritional program in HIV care settings, and negatively influenced monitoring, supervision and program follow up. It has also resulted in challenges to the supply and distribution of the nutritional support, and a reduction in training and, financial assistance for health providers. The reduction of local and international donor interest in the nutritional program may be due to a change in priorities, with other programs and geographic areas now considered more in need of assistance, along with decreasing global health investment (Wang et al. 2016). This has affected monitoring and evaluation and therefore there is little evidence to identify operational issues which may be related to decreasing NGO interest and lack of core funding.

<u>Sarriot et al. (2004)</u> pointed out, sustainability is a key concern when health programs rely heavily on NGOs and donor organisations. This was reaffirmed by this study. The scope and interest of NGOs in supporting the health system of a country can contribute to fragmentation and less sustainable health programs (<u>Shandra, Shandra and London 2010</u>), which may also be relevant to the nutritional program in Ethiopia. In addition, another study conducted in Mozambique indicated that although a Code of Conduct for NGOs stipulated that they should work within the priorities identified by countries' Ministries of Health, lack of adherence to the Code by NGOs contributed to the overall weakening of health systems (<u>Pfeiffer 2003</u>).

It is suggested that for health programs to be sustainable, health systems should work towards reliance on locally available resources while collaborating with NGOs to strengthen health systems (Rosenberg, Hartwig and Merson 2008). Strengthening local capacity building and establishing local and international partnerships with NGOs could help to address challenges related to funding and sustainability of the nutritional program in HIV care setting.

Management and implementation of the nutritional program

A number of management and implementation challenges constrained utilisation of the nutritional program. Technical difficulties, such as poor supply management and distribution of nutritional support, were important contributors to low utilisation. In addition, HIV programs including the nutritional program suffered from the occasional lack of ART medication and the nutritional support because of the lack of proper distribution and supply management. It was beyond the scope of the current study to explore and examine supply issues in the nutritional program but this could be an important area of investigation for future study. A study in South Africa found nutritional programs in HIV care were constrained by similar issues, such as difficulties of logistics (Heller et al. 2000). Findings of this study were also consistent with a review conducted in developing countries which identified procurement, supply chain management and inventory control systems as major challenges for nutritional programs (Tang et al. 2015).

Proper monitoring and evaluation is important for strengthening programs and health systems (Ekouevi, Karcher and Coffie 2011; Nash et al. 2009). However, this study showed that the nutritional program in HIV care settings was impeded by poor monitoring and evaluation systems. The current monitoring system includes indicators such as the number of people undergoing nutritional assessment and number of people enrolled in the nutritional program, with no indicator measuring nutritional program outcomes. Nevertheless, there has been a positive move in the Ethiopian national health information system to incorporate nutritional program indicators, including key nutritional performance indicators (Federal Ministry of Health of Ethiopia 2012).

6.3.5 Sociocultural barriers and enablers

Sociocultural factors were key barriers constraining the utilisation of the nutritional program. These included poverty and poor livelihood, food insecurity, cultural meaning of the nutritional support, religious issues such as fasting, and stigma and discrimination.

Food insecurity, poor livelihood and poverty

Poverty and poor livelihood are widespread among people living with HIV because of various social factors (<u>Uthman 2008</u>). Poverty is worst in households affected by HIV or AIDS (<u>UNAIDS 2018b</u>), indicating the importance of considering the social determinants of health and social policy level factors in nutritional programming in HIV care settings.

Food security involves availability, access to and utilisation of foods (<u>Barrett 2010</u>) and food insecurity is described as the lack of access to adequate quantities and quality of food (<u>Swindale and Bilinsky 2007</u>). Food insecurity is widespread in the Ethiopian general population (<u>Belachew et al. 2011</u>; <u>Van der Veen and Gebrehiwot 2011</u>) and particularly among people living with HIV (<u>Tiyou et al. 2012</u>). Qualitative findings of this study indicated that food insecurity was common among study participants enrolled in the nutritional program, affecting the program in a number of ways. Several studies have highlighted the high rates of food insecurity among people living with HIV (<u>Kuria 2010</u>; <u>WFP, WHO and UNAIDs 2008</u>). For example, a study conducted in Malawi among adults living with HIV enrolled in a nutritional program reported that poor nutritional outcomes were seen among those with the greatest food insecurity (<u>Bahwere et al. 2011</u>). Although one study conducted in Ethiopia highlighted that food insecurity was less likely to contribute to non-response among those enrolled in the nutritional program (<u>Sadler et al. 2012</u>), other studies, including the current study, have shown that household food insecurity was a deep-rooted challenge to the effectiveness of the nutritional program in HIV care settings.

Food insecurity affected motivation for enrolment in the program, nutritional outcomes and counselling, and maintenance of nutritional wellbeing among study participants. For example, food insecurity was identified as a key barrier in applying nutritional counselling recommendations to improve and maintain consumption and diversification of food. Food insecurity also contributed to the sharing and selling of the nutritional support, delaying graduation or increasing the likelihood of non-response to the nutritional program. A study from Malawi likewise indicated that food insecurity had contributed to selling and sharing of the nutritional support by participants (Rodas-Moya et al. 2016).

Within an environment of food insecurity and poor livelihood, patients who recovered while on the program were more likely to face relapse of undernutrition and subsequent re-enrolment into the program, which was highlighted in the qualitative findings of the current study. Consistent findings were reported by Bahwere et al. (2011), where relapse of undernutrition was most likely among those with the highest levels of food insecurity. In addition, relapse of undernutrition in food insecure households may be attributed to the poor quality of food (Bahwere et al. 2011), indicating the importance of food quality in addressing food insecurity. A similar review also indicated that nutritional programs in HIV care were ineffective in the presence of food insecurity (de Pee and Semba 2010).

Marmot et al. (2008) argued that poverty is an essential determinant of poor health outcomes particularly in low-income resource settings. In the current study, food insecurity was embedded in poverty and poor livelihood. Drivers of poverty and poor livelihood identified in the current study were job loss and lack of employment because of illness, stigma and low educational attainment, which subsequently contributed to food insecurity and nutritional program ineffectiveness. Despite contextual differences with Ethiopia, in a study conducted in Kenya Ongondi, Ayodo and Adoka (2016) found that meal size was influenced by social factors such as occupation, family size and education, and concluded that poverty was a major constraint on nutritional program effectiveness.

While people living with HIV suffer from broad socioeconomic problems, the nutritional program has a narrow focus on improving weight among undernourished people living with HIV. The use of BMI as the sole criterion for enrolment into the nutritional program made it difficult to identify participants' level of poverty and food insecurity and to plan for other social supports. This has contributed to reduced effectiveness of the nutritional program such as lack of adherence, sharing and selling of the nutritional support, issues with nutritional counselling, and relapse of undernutrition.

A study from Uganda showed that programs addressing poverty and livelihood conditions were effective in addressing nutritional outcomes of people living with HIV (Yager, Kadiyala and Weiser 2011). The nutritional program examined in the current study had limited follow up plans and interventions for people who graduated from the program, such as income generating activities and other livelihood programs. Generally, holistic nutritional programs that involve treating undernutrition, addressing household food insecurity and sustaining nutritional wellbeing need to be considered at all levels of program entry, completion and continuation.

Quantitative findings in this study showed that people living in urban areas were more likely to default and become non-respondent than those living in rural areas, which may be related to urban poverty and food insecurity as discussed in **sub-section 6.2.1**. The interviews revealed that some people from rural areas appeared to have access to economic supports including land ownership and other benefits such as social safety nets, which were not reported by people in urban areas. Such supports are outlined in the Ethiopian national nutritional program but further details on specific implementation strategies in urban and rural areas are lacking (Government of the Federal Democratic Republic of Ethiopia 2013–2015). A study from Uganda also reported that livelihood programs involving farming were not applicable in urban areas (Yager, Kadiyala and Weiser 2011). Hence, different approaches should be used to address poverty for people living with HIV in urban and rural areas to improve effectiveness of nutritional programs and nutritional wellbeing of people living with HIV.

One of the key findings of this study was that some study participants attempted to delay nutritional recovery and graduation from the nutritional program. Delaying nutritional recovery and multiple enrolments into the program were mechanisms to prolong access to the nutritional program and were driven by poor socioeconomic status and food insecurity.

Poverty and poor livelihood were exacerbated by low levels of education and skills among study participants, contributing to an absence of sustainable and reliable income and thus to food insecurity. This finding is consistent with the study by Marmot et al. (2008)) which demonstrated that education and fair employment are crucial determinants of health outcomes. According to Marmot et al. (2008), material poverty is the fundamental determinant of poor health status and poor health outcomes. In addition, access to education and employment can also be considered as social policy factors in the socioecological model (Mehtälä et al. 2014) that may contribute to food insecurity and negatively affect utilisation of the nutritional program at various levels. In addition, household poverty and other social determinants of health are common challenges for people living with HIV (UNAIDS 2018b; Uthman 2008) and should be important considerations in nutritional programs in HIV care settings.

Cultural meaning of the nutritional support

Food choices and eating behaviours are influenced by "biological, anthropological, economic, psychological, sociocultural, home economics related and situational determinants" and involve "identity, communication, community and spirituality issues regarding food" (Gedrich 2003, p 232-234). According to findings of this study, the nutritional support was unlike local and culturally familiar foods in terms of its packaging, taste and preparation, suggesting the nutritional support did not fulfil the identity, communication, community and spiritual elements of food in the Ethiopian context.

The Ethiopian traditional food menu favoured by adults is hot and spicy. Since Plumpynut was originally designed to treat undernutrition in children (Cames et al. 2016; Valid International 2006), it is sugary in taste and thus was not well accepted by adults in this study. In addition, the nutritional support lacked resemblance to local foods in terms of texture and palatability. Studies conducted in Malawi and Thailand indicated that nutritional supports prepared locally were more acceptable and resulted in quicker weight gain and improved overall wellbeing in adults living with HIV (Bahwere, Sadler and Collins 2009; Rodas-Moya et al. 2016). For instance, according to Bahwere, Sadler and Collins (2009), locally made nutritional support was totally different in terms of packaging, content and taste from the standard nutritional support (Plumpynut/sup). As indicated in sub-section 6.3.4, the nutritional support used in HIV care in Ethiopia is imported or locally made with similar branding and packaging.

Generally, <u>Martinez et al. (2014)</u> suggested consideration of local context and use of locally available and acceptable nutritional supports was vital for improving nutritional program effectiveness. However, it is important to note that even if adults did not like the food for different reasons, they wanted to stay in the nutritional program to get the nutritional support and exchange it for other foods by selling or sharing it in the family.

Food practices and perceptions were highly related to culture, indicating the need to consider the sociocultural context when introducing nutritional support in HIV care services (Olsen et al. 2013). The social and cultural factors influencing utilisation of the nutritional program fit into the broader context where the meanings attached to nutritional support are not an individual matter but are embedded in the community's culture and food practice. According to the social determinants of health model, culture is one of the distal determinants of health (Raphael 2006) and this can help explain the influence of culture and food practice on the nutritional program.

Fasting (abstaining) from animal products is considered a major religious responsibility by members of the Ethiopian Orthodox Church (Belwal and Tafesse 2010; Zellelew 2014). This involves avoiding meat, egg and dairy products for at least 190–250 days a year, including every Wednesday and Friday. This study found that religious issues such as religious acceptability of the nutritional support and fasting were important barriers to utilisation of the nutritional program because a significant number of participants in the current study were suspicious about the religious acceptability of the nutritional support. Lack of knowledge and understanding of the contents of the nutritional support contributed to questions about its religious conformability. According to many study participants, religious fasting was considered a means for healing their HIV and improvement from illness. For this reason, because the nutritional support was believed to contain dairy products, 70% of adults and 40% of children living with HIV enrolled in the nutritional program ceased consumption of the nutritional support on fasting days to fulfil religious obligations.

In another study in southwestern Ethiopia, religious fasting was not a problem for utilisation of a nutritional support (ready to use supplementary foods). This was because study participants gave priority to their health rather than to religious practices such as fasting, and the nutritional support was considered as a medicine where social norms such as fasting and sharing were seen as not applicable (Olsen et al. 2013). Thus, there may be contextual differences in the importance of fasting between the current study and the study conducted in southwestern Ethiopia, where the majority of the population is Muslim while in the northern part of Ethiopia, where the current study was conducted, is predominantly Christian. Fasting as a religious responsibility was less of a concern in children because they were exempted from fasting but was important in adults and a major reason for default from the nutritional program, contributing to problems of program effectiveness.

Religious leaders played an important role in determining whether adult participants used the nutritional support during fasting. Despite the importance of religious beliefs as a constraint in the nutritional program, program managers in the current study showed that engagement with regional and local religious leaders may improve utilisation. Religious practices such as fasting are experienced as group norms and practices and peer pressure may force individuals to obey these group norms. According to the social determinants of health (Marmot et al. 2008) and the socioecological model (Bronfenbrenner 1996; Golden and Earp 2012), health is determined by the social environment wherein the individual grows and develops. Religious environment, community norms and culture in the current study were crucial factors affecting the utilisation of the nutritional program. Thus, nutritional programs targeting people living with HIV should consider the social environment, such as religious issues, through engaging religious leaders to improve utilisation and effectiveness of programs.

Stigma and discrimination

Stigma and discrimination associated with enrolment emerged as a barrier to the nutritional program. Link and Phelan (2001, p 367) define stigma as "the co-occurrence of its components—labelling, stereotyping, separation, status loss, and discrimination—and further indicate that for stigmatisation to occur, power must be exercised". Deacon (2005, p 15), based on (Herek, Capitanio and Widaman 2002), defined stigma in HIV and AIDS as an "enduring attribute of an individual infected with HIV that is negatively valued by society and thus disadvantaged people living with HIV". HIV is a chronic condition evaluated undesirably within a society so that the condition is considered as social deviance from social morality (Ochtera R 2012) fuelling stigma, discrimination and isolation among people living with HIV. Link and Phelan (2001, p 382) argue that "stigma is likely to be a key determinant of many of the life chances from psychological well-being to employment, housing, and life itself".

Participants were afraid of the consequences of stigmatisation in their business and/or employment prospects, access to resources such as housing and social lives of disclosure of their positive HIV status. Another study from Ethiopia reported fear of stigma and discrimination as the main reason for non-disclosure of positive HIV status (Seid, Wasie and Admassu 2012). Potential life disruptions, social reactions and a concern about diminished roles in the household were barriers to disclosure of positive HIV status to a spouse, other family members, neighbours and the neighbourhood (Gadisa et al. 2017). Findings of this study similarly highlighted that concerns about social isolation and rejection by friends and the wider community through the disclosure of the positive HIV status were common among participants.

Many studies have cited that HIV status disclosure is a crucial precursor for the utilisation of HIV and other services (<u>Akilimali et al. 2017</u>; <u>Obermeyer, Baijal and Pegurri 2011</u>). <u>Akilimali et al. (2017)</u> found that default from HIV services was more common among those who did not disclose their positive HIV status compared with those who disclosed. <u>Arrivé et al. (2012)</u> found that disclosure of positive HIV status likewise improved retention in HIV care.

Disclosure of positive HIV status varied by the nature of relationships with the target person. Significant numbers of study participants disclosed their positive HIV status to family members, which they perceived as less stigmatising than disclosing beyond family members. A study from Uganda also found that the reasons for disclosure and non-disclosure varied by the disclosure target person (Ssali et al. 2010).

There were also differences between adults and children on the issue of disclosure, with fear of disclosure being more of an issue in adults. While most children enrolled in the nutritional program knew their positive HIV status, some children did not and the reason given by caregivers for not disclosing was fear of the child's reaction to a positive HIV status at a young age. This was also found by Wright et al. (2017), who reported there was a lack of resources and no national disclosure policy for children living with HIV. Another study conducted in Ethiopia found similar reasons for not disclosing the positive HIV status of children, such as fear of negative emotional consequences in the child (Abebe and Teferra 2012).

The nutritional support and its contribution to stigma

Despite variations in the target of disclosure, non-disclosure hindered utilisation of the HIV service in general and the nutritional program in particular, with a widely held belief in the community that the nutritional support was related to HIV. Those who did not disclose their positive HIV status believed that the community may connect nutritional support with HIV and were concerned about being discovered with the nutritional support. A number of other studies in Ethiopia similarly highlighted the link communities made between the nutritional support and HIV status and the fear of disclosure if seen with the nutritional support (<u>Hussien et al. 2015</u>; <u>Olsen et al. 2013</u>).

In this way, stigma related to HIV has the potential to constrain utilisation of nutritional programs. In the current study, different dimensions or aspects of stigma affected utilisation of the nutritional program and other HIV services. This included the nutritional support itself being linked to HIV generated fear of being seen transporting, eating or disposing of it – which potentially lead to selling it and defaulting from the program. Enrolment in the nutritional program required more frequent visits to the health facility than for other HIV services such as ART. Thus, participants were concerned with being discovered because they had to visit the health facility every month for three to six months, and this was a key concern identified in the current study. The role of nutritional programs in enhancing HIV related stigma and discrimination has been identified in many other studies but these related stigma to the nutritional support only (Cames et al. 2016; Dibari et al. 2012; Hussien et al. 2015; Olsen et al. 2013; Ongondi, Ayodo and Adoka 2016). According to findings of this study, the nutritional support was revealing because of its distinctive packaging, a point made in studies in different contexts in eastern Africa such as Ethiopia and Kenya that reported the link between consumption of nutritional support and HIV disclosure (Dibari et al. 2012; Hussien et al. 2015; Kebede and Haidar 2014).

Wasting syndrome is one of the AIDS defining conditions (<u>Salomon, De Truchis and Melchior 2002</u>) and is often perceived as exposing and stigmatising by people living with HIV (<u>Varas-Díaz, Toro-Alfonso and Serrano-García 2005</u>). There is some evidence showing enrolment in HIV care such ART has helped patients in improving their weight and perhaps reduce stigma (<u>Horter et al. 2019</u>). In the current study participants acknowledged the importance of the nutritional program in improving their nutritional status and overall well being but there were no accounts of participants noting that involvement in the program and their use of Plumpynut helped reduce stigma and stigmatising experiences.

There were differences between adults and children in terms of the nutritional program's contribution to stigma through the nutritional support in the current study. The nutritional support was not a major concern of stigma and discrimination in children because Plumpynut/sup is also given to undernourished children aged under five who are HIV negative (Valid International 2006). This finding was consistent with the findings of other studies that there were few concerns about the nutritional support creating risk of disclosure in children living with HIV (Cames et al. 2016; Ickes et al. 2012).

6.4 Conceptualising the challenges of the nutritional program using the SEM model

Highlights of the socioecological model

The socioecological model (<u>Stokols 1992</u>) described in Chapter 2 (**sub-section 2.9.1**), is a multilevel model which helps in understanding the overarching influences of various factors on health behaviours, health outcomes, and their implications on policy and practice (<u>Stokols 1992</u>) The levels of influence of various factors on health behaviours and outcomes include individual, inter-individual, institutional, community, and social policy (<u>McLeroy et al. 1988</u>).

As shown below, there are dynamic relationships between individuals and their social, physical and policy environments. Individual perceptions, attitudes and practices have an impact on the cultural and social environment in which the nutritional program is implemented, which in turn influences program utilisation and nutritional outcomes. Similarly, the social and policy context under which adults and caregivers live, and in which the nutritional program is implemented affects individual behaviour and nutritional program outcomes and utilisation.

Using the socioecological model, **Figure 6.1** illustrates the inter-relationship between different levels of influences on nutritional outcomes and the utilisation of the nutritional program. The levels of analysis as presented in the diagram below are defined as follow:

- 1. **Individual level factors**: the perceptions, beliefs and understanding of adults and caregivers about their health situation, nutrition and the nutritional program in HIV care.
- 2. **Inter-individual level factors**: the factors that are within the personal network of the individual with HIV that influence utilisation of the nutritional program.
- 3. **Institutional level factors**: the health service issues that influence utilisation of the nutritional program.
- 4. **Community level factors**: the social, cultural and religious environment where the individual lives that influence the utilisation of the nutritional program.
- 5. **Social policy level factors:** the broader health system and policy environments that have an impact on the nutritional outcomes and utilisation of the nutritional program.

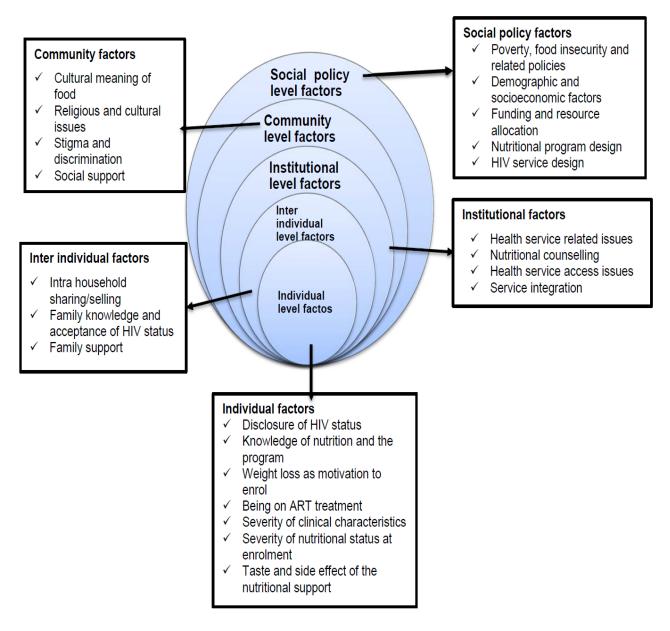


Figure 6.1: Five-level socioecological model used to conceptualise the challenges to nutritional programs in HIV care (Adapted from (<u>Bronfenbrenner 1996</u>; <u>Chimphamba et al. 2012</u>; <u>McLeroy et al. 1988</u>).

This model and examples of interrelationships between various factors in relation to the nutritional program are discussed in detail below:

Individual level factors and interrelationships

Taste and side effects of the nutritional support were factors identified influencing utilisation of the nutritional program. Individual's taste preferences are determined by the individual's identity and food culture within the broader community level. Individual experience of what a certain food such as the nutritional support tastes like is shaped by the identity and food culture to which the individual is affiliated i.e. 'like and dislike' of taste of food is closely linked to the food culture of the community within which somebody lives (Gedrich 2003). The nutritional support used in the nutritional program has little modification or contextualisation to make it acceptable for individuals. The selection and recommendation of Plumpynut/sup goes back to the policy environment in which the nutritional program is designed. This is an example of where policy factors can indirectly affects practices at the individual level.

Another factor related to the nutritional support as found in this study was its side effects. In its simplest picture, side effects of nutritional support may be considered as an individual level factor directly related to individual cognition and perception (McLeroy et al. 1988) about the nutritional support. Looking at the broader picture, using the socioecological model, one can link the issues in relation to side effects to institutional level factors such as the design and implementation of comprehensive nutritional counselling where appropriate information should be provided to individuals to better understand the potential side effects and ways to manage them. This demonstrates the interaction between various level factors in the way individuals practice (Baral et al. 2013; McLeroy et al. 1988).

Using the socioecological model, factors such as knowledge about the causes of undernutrition, and motivations for enrolment such as weight loss, were individual level factors related to individual knowledge and cognition (McLeroy et al. 1988; Stokols 1996). These individual level factors can also interact with institutional level factors like nutritional counselling and education, where institutional structure, culture and operational issues were deemed as important determinants of health behaviour and outcomes (McLeroy et al. 1988). In addition, in the socioecological model individual motivations for enrolment such as lack of adequate food in the household were interlinked with inter-individual level factors such as sharing and selling, also with community level factors such as sharing culture, and social policy level factors such as food insecurity and poverty (Chimphamba et al. 2012; McLeroy et al. 1988).

The clinical and nutritional factors that contributed to ineffectiveness of the nutritional program included WHO clinical stage, functional status and nutritional status at enrolment are better explained as individual level factors. These factors were mainly related to the individual's biological response to the infection and the decision to get treatment for such conditions, as clearly implied in the socioecological model (McLeroy et al. 1988; Robinson 2008). Poor clinical conditions and severe acute undernutrition at enrolment contributed to ineffectiveness of the nutritional program because of the clinical effects of the HIV condition (Katona and Katona-Apte 2008), where severe clinical and nutritional effects of infections played a key role in influencing the effectiveness of the nutritional program. Severity of clinical conditions is also related to institutional level factors such as poor identification and treatment of severe clinical illness at the health facility. Therefore, the clinical and nutritional characteristics of the individual influenced the nutritional outcomes and utilisation of the nutritional program through both individual level (the individual response to infection) and institutional level factors (potentially poor identification and management of infection).

Inter-individual level factors and interrelationships

Inter-individual level factors that influenced the nutritional outcomes and utilisation of the nutritional program were sharing and selling of the nutritional support, disclosure of HIV status and family acceptance and family support provided to the individual. Individuals enrolled in the nutritional program were recommended not to share the nutritional support, but in Ethiopia food sharing is a common cultural practiced within the family. In addition, adults and caregivers often lived in households experiencing food insecurity, which was a major driver for sharing the nutritional support in the current study. Selling of the nutritional support was also related to family issues in the household that can be related to household food insecurity. Informed by the socioecological model, it can be argued that sharing and selling of the nutritional support influenced the nutritional program through various drivers that fall across the inter-individual, community and social policy level factors (Golden and Earp 2012; McLeroy et al. 1988; Robinson 2008).

The nutritional support was taken home by participants where its consumption was fundamentally influenced by the potential disclosure of positive HIV status and the risk that this might threaten family acceptance and support. Family environment can influence utilisation of the nutritional program, and although disclosure of positive HIV status is an individual decision, it often depends on the acceptance by the family and broader community. Similarly, individuals might face difficulties in using the nutritional support in the absence of family support for the nutritional program in particular and HIV status in general. The socioecological model emphasises the importance of family structure in influencing health behaviours and outcomes (Chimphamba et al. 2012; Robinson 2008).

Institutional level factors and interrelationships

Institutional level factors in the socioecological model include organisational structure and culture which influence health behaviour and outcomes for the individual (Robinson 2008). According to McLeroy et al. (1988), social institutions can have a critical influence on individual health. In this study, the elements of health facilities were significant factors in the success or otherwise of the nutritional program. Nutritional counselling was directly related to health system issues but in the SEM, it is interlinked with various other levels. Broadly, the presence of nutritional counselling in HIV care was essential to the nutritional program, despite the setbacks in providing information about the use and benefits of the nutritional program to individuals. However, institutional level challenges such as offering one session only, of short duration, the lack of counselling guidelines, and lack of ongoing training of health providers together with policy level factors such as the medicalised orientation of the nutritional counselling were limiting its effectiveness. In addition, the absence of goal oriented nutritional counselling guidelines contributed to unstructured and uncontextualized nutritional counselling in HIV care settings. Poor nutritional counselling can further influence individual understanding about the nutritional program, thus contributing to issues of utilisation. Furthermore, in the socioecological model acceptability and applicability of nutritional counselling can be considered as an individual level factor influencing utilisation of the nutritional program, but also impacted by the broader socioeconomic environment that people live in not allowing them to apply counselling advices such as consumption of nutritional food (McLeroy et al. 1988; Robinson 2008).

Other health service factors that influenced the utilisation of the nutritional program were convenience of the service area, trust in health providers and strategies used to improve adherence and waiting times. These factors created a favourable environment in the health care setting which promoted utilisation by people living with HIV. Similarly, Golden and Earp (2012) indicated the importance of institutional level factors such as modification of institutional environments and services to improve effectiveness of a program. Some concerns around integration and the lack of skills and experience of health providers were also institutional level factors influencing their capability to provide appropriate counselling advices, and in turn individuals' knowledge and their utilisation of the nutritional program. Institutional level factors, such as issues of integration, were also related to both institutional and policy level factors, such as the absence of mechanisms to ensure programmatic integration at program level because of poor services. This demonstrated the dynamic nature of health service factors that were influenced by policy level factors while themselves influencing individual level acceptability and understanding about the service, demonstrating the interplay of different factors at various levels of the socioecological model (Bronfenbrenner 1994; Stokols 1996).

Community level factors and interrelationships

According to the socioecological model, community level factors including formal and informal social networks influence health behaviour and outcomes (Chimphamba et al. 2012; McLeroy et al. 1988). Key community level factors identified in the current study included the cultural meaning of food, religious and cultural issues related to food, and stigma and discrimination. Religious and cultural issues around fasting and the substantial impact of stigma and discrimination on individuals' use of the program were good examples of this. The nutritional program in HIV care was implemented within a broader sociocultural environment where religious and cultural factors had a huge impact on community norms, eating patterns, and preferences for different foods (Chimphamba et al. 2012; Robinson 2008), and thus on the acceptance and utilisation of nutritional support. Religious practices also influence the uptake of nutritional counselling recommendations and determine the cultural meaning of the nutritional support used in the program. The socioecological model assists to comprehend this complex interrelation between individual behaviour in relation to program utilisation, and cultural belief and religious practices.

It is argued that social relationships and strong supportive networks are one social determinant of health that leads to improved health (Wilkinson and Marmot 2003). Furthermore, community level determinants such as established norms, values, standards and social networks are crucial community level factors that influence health behaviours and outcomes in the socioecological model (Chimphamba et al. 2012). HIV community support groups create an opportunity for individuals to receive nutritional information, counselling and social services. In the current study, individuals who were not members of community support groups were more likely to have relapse of undernutrition. Community support groups also encourage patients to disclose positive HIV status and work with families of affected individuals to enhance family support. Thus, such support may provide opportunities to maintain nutritional status after nutritional recovery and minimise relapse of undernutrition. HIV community support groups can also be an inter-individual level factor by facilitating individual disclosure of positive HIV status mainly to families and partners and thereby influence utilisation of the nutritional program. According to a study conducted in South Africa, community support groups enhanced disclosure of positive HIV status to family members through creating conducive environment between the HIV positive person and his or her family members (Wouters et al. 2009). In addition, community support groups play a vital role in reducing stigma and stigmatising attitudes towards people living with HIV and improve utilisation of HIV care (Bateganya et al. 2015).

HIV stigma and discrimination emanated from people's perception about the HIV disease and deviance from community norms and rules, and the socioecological model highlights the influence of such norms on health behaviour and outcomes (Chimphamba et al. 2012; McLeroy et al. 1988). The nutritional program was implemented in a community where stigma and discrimination related to HIV were common, and enrolment in the nutritional program was closely linked with being HIV positive. In the socioecological model, stigma and discrimination have effects at various levels (Robinson 2008; Stokols 1996) and influence access to services by diminishing individual dignity. In this study, stigma and discrimination constrained utilisation of the nutritional program because of the community's view towards HIV and the nutritional program and the individual's perceived stigma. A study by Alemu et al. (2013) highlighted that stigma and discrimination affected utilisation of health services by creating shame and fear of being seen when visiting the health facility when positive HIV status had not been disclosed, a scenario which exactly fits with the experience of adults and caregivers in the nutritional program in HIV care in the current study. The health service and broader policy environment can also play a vital role in mitigating stigma and discrimination through creating an environment to advocate inclusiveness and fight stigmatising and discriminatory actions.

Social policy level factors and interrelationships

Social policy level factors in the socioecological model include the policy context (McLeroy et al. 1988; Robinson 2008; Simons-Morton, McLeroy and Wendel 2012). The context in Ethiopia within which the nutritional program was designed and implemented was characterised by poverty, poor livelihood and food insecurity. These contributed to the lack of understanding about the nutritional program and enhanced sharing and selling of the nutritional support, which in turn affected program outcomes and utilisation. While the underlying determinants of undernutrition in HIV are poverty, poor livelihood and food insecurity, nutritional programs in HIV care focused on treating undernutrition, which demonstrates a clear policy level gap. Furthermore, it is argued that poverty and poor livelihood are explicitly essential in creating an environment of inequitable access to health services (WHO Commission on Social Determinants of Health 2008) and can be applicable in the case of the nutritional program in HIV care. Poverty and poor livelihood limit people's access to basic education, health services and basic amenities and lead to the poorest health outcomes (Wilkinson and Marmot 2003, p 16-17). They are also closely linked to food insecurity that shapes people's behaviour and practices, including appropriate use of nutritional supports, sharing with other members of the family and selling to meet other household needs (Woolf and Braveman 2011).

Demographic and socioeconomic characteristics were individual attributes but were closely related to the broader social order and economic factors that were beyond the control of any individual. In the SEM, demographic and socioeconomic conditions are treated as overarching factors related to social policy factors. For instance, in the study, differences in policy environment between urban and rural residents contributed to the challenges of the nutritional program, where people living with HIV from urban areas were more likely not to complete and to be non-respondent. A key issue in the current study was the presence of local policies targeting poverty, poor livelihood and food insecurity for people living with HIV in rural areas, while nothing equivalent was reported in urban areas. According to Marmot et al. (2008), urban residents are disproportionately prone to poverty because of the fast and unplanned growth of urbanisation. Hence, urban poverty may contribute to food insecurity and ineffectiveness of nutritional programs in HIV care. According to McLeroy et al. (1988), social policy level factors include local, regional and national laws and policies, including their interpretation and enforcement. It is also speculated that living in urban areas may be related to selling of the nutritional support, as was reported by some participants in the qualitative study. Thus, place of residence was an overarching factor between policy level factors such as poor implementation of local, regional or national policies to support people living in urban areas, and community level factors such as the urban neighbourhood facilitating sale of the nutritional support (McLeroy et al. 1988; Stokols 1996).

Other social structures such as educational and employment status also influenced effectiveness of the nutritional program in HIV care. Lower educational status contributed to issues of nutritional program effectiveness through its influence on employment opportunities, income and understanding about the nutritional program. According to Nagata et al. (2012) and based on a study by Mwaniki (2006), poor educational status was a determinant of food insecurity, which was also a contributor to nutritional program ineffectiveness. In addition, poor educational status contributes to low-income, skills and marginalisation (Marmot et al. 2008). Woolf and Braveman (2011">Moolf and Braveman (2011">Moolf and Braveman (2011">Moolf and Braveman (2011"), p 1852) argued that "inadequate education and living conditions ranging from low-income to the unhealthy characteristics of neighbourhoods and communities can harm health through complex pathways".

Similarly, while unemployment and lower educational status are generally related to poor health outcomes and premature death (Wilkinson and Marmot 2003) in the current study being employed was associated with poorer outcomes from the nutritional program. According to Marmot et al. (2008, p 1663), "employment can provide financial security, social status, personal development, social relations, self-esteem and protection from physical and psychosocial hazards". Furthermore, the "nature of employment is crucial in predicting health as mentioned above that people working in the informal sector mainly in urban areas have no legal protection which may contribute to poorer health outcomes" (Marmot et al. 2008, p 1663). According to the qualitative findings, a misconception about the nutritional program was identified among those who were employed and earning a decent wage, namely that the nutritional support was only for those who were poor, and this can be considered an individual level factor influencing utilisation.

Gender influenced the utilisation of the nutritional program in HIV care settings. Being female indirectly influenced program effectiveness through greater sharing of the nutritional support among family members. Gender is a determinant of health that influences "power, resources, entitlements, norms and values, and the way in which organisations are structured" (Marmot et al. 2008, p 1666). There is also gender disparity in the distribution of and vulnerability to HIV infection. For instance, women have a 60% higher risk of contracting HIV infection than men (Magadi 2011; Tsai and Subramanian 2012). Further to this, community norms and cultures are stronger among females than males. Hence, in the socioecological model, gender is as acting at multiple levels such as inter-individual and community levels through culture, food sharing culture and differences in power, resource and entitlements (Chimphamba et al. 2012).

Broader health system issues and health policy were factors that interacted with the clinical, institutional and health service factors to influence nutritional outcomes and utilisation of the nutritional program. The nutritional program was implemented in a health system setting constrained in terms of access and implementation issues. This influenced program effectiveness both directly and indirectly through drivers at various levels in the socioecological model. Important factors were distance, lack of funding and supply of the nutritional support, technical issues, clinical guidelines, scope of the program, access and implementation issues. According to the socioecological model (Reifsnider, Gallagher and Forgione 2005), problems of access can be considered as a broader policy level issue where the nutritional program was not as decentralised to the same extent as other HIV services. Economic circumstances have an impact on people's practices where poor socioeconomic status is a fundamental barrier to health service utilisation (Marmot et al. 2008). The WHO Commission on Social Determinants of Health (2008) argued that the poor have less access to basic health services and, using the socioecological model, helps to unpack the interaction between health system and structural factors with various institutional level factors.

The nutritional program is implemented in a health system where funding and resource allocation is mainly dependent on NGOs and their withdrawal from HIV services in general and the nutritional program in particular impacted the program. Over the last 10 years, NGOs have played a valuable role in the nutritional program through funding, monitoring and evaluation. These activities can be placed at various levels in the socioecological model. However, challenges related to the withdrawal of NGOs and lack of institutional transfer of knowledge and skills from NGOs to the health system is a policy matter. For instance, the Ethiopian health policy stipulates two key points about the role of NGOs in the health system. The first is the importance of mobilising internal and external resources to promote self-reliance, and the second is the necessity of the health system to work in partnership with NGOs (The Transitional Government of Ethiopia 1993). However, there is no governing strategy to force NGOs in Ethiopia to assist in strengthening the country's health system. Research has highlighted that the lack of alignment with national health system priorities and vertical orientation of NGOs has negatively affected the sustainability of health programs (Le Loup et al. 2009; Mussa et al. 2013). The policy level factors also contribute to institutional level problems such as issues related to the nutritional counselling and skills of health providers. This is because the expertise and funding provided by NGOs was highly involved in training and capacity building of health providers about the nutritional program and nutritional counselling, monitoring and evaluation of it and supply management of nutritional support. NGOs withdrawal has influenced institutional characteristics as stated in the socioecological model (McLeroy et al. 1988). However, the financial and technical support provided to health system is vital despite the issues related to the mechanisms NGOs support health system.

The medicalised orientation of the nutritional program and determination of enrolment and exit criteria are policy level decisions that influenced nutritional outcomes and utilisation of the nutritional program. It is a policy level decision that the nutritional program used BMI alone to enrol and discharge adults from the nutritional program without any consideration of other issues while many of the nutritional problems of people living with HIV went beyond the individual's BMI. This limited the scope of the nutritional program to treat undernutrition comprehensively among people living with HIV.

In conclusion, the socioecological model is used to demonstrate the dynamic interplay of the various factors that influenced nutritional outcomes and utilisation of the nutritional program. First, individual knowledge and understanding about the nutritional program, motivation for enrolment, and continuous use of the nutritional program influenced nutritional program utilisation. Second, inter-individual level factors such as sharing or selling, HIV status disclosure and family acceptance affected utilisation of the nutritional program through interactions with community level factors because of the food sharing culture and selling. Third, a range of institutional level factors such as nutritional counselling, health service factors and access to health services influenced utilisation of the nutritional program through a strong interaction with policy and individual level factors. Fourth, community level factors such as culture and religion, the cultural meaning of the nutritional support, community support, stigma and discrimination were factors that influenced nutritional program outcomes and utilisation through interaction with individual level factors. Fifth, poverty and poor livelihood directly or through demographic and socioeconomic characteristics influenced nutritional outcomes and utilisation of the nutritional program. Finally, health system factors such as resource allocation and program design were policy level factors influencing nutritional outcomes and utilisation of the nutritional program in HIV care settings. As highlighted above, while these levels are presented independently, there is significant overlap and nesting of factors and this understanding helps unpack the complex issues influencing the outcomes of the nutritional program in Ethiopia.

The social determinants of health model is also used to explain the broader impact of some demographic and socioeconomic factors such as employment, gender and educational status on the nutritional program. Female gender and lower educational status have contributed to the problems of effectiveness of the nutritional program due to their impact on the distribution of power, resources and other cultural issues (sharing culture and practice more common among females).

6.5 Methodological considerations

6.5.1 Strengths of the study

This study has advanced knowledge of nutritional programs in HIV care in low resource settings. Explicating the determinants of nutritional outcomes among people living with HIV enrolled in a nutritional program and the barriers to and facilitators of program utilisation is essential to help guide future policies and ensure optimal nutritional and health outcomes for people living with HIV. In addition, this study will inform further programmatic research using data routinely collected in nutritional programs in HIV care and other relevant programs. The study was conducted in the real-life context of programmatic implementation in Ethiopia in a resource constrained area. This facilitated examination of the contextual and health system challenges and the individual patient level challenges of the nutritional program.

The study has triangulated various methods and different participant groups to enhance the study credibility. The study employed mixed research methods involving both the qualitative and quantitative studies, in multiple groups of participants and at different sites to explicate the challenges of the nutritional program. While the quantitative study was used to measure the effectiveness of the nutritional program and the demographic and socioeconomic, immunological and clinical, nutritional and anthropometric correlates of it, the qualitative study enabled identification of the barriers to and facilitators of the nutritional program. The use of theories facilitated an in-depth understanding of nutritional program challenges and their interactions in HIV care settings. The models also assisted with explaining, understanding and interpreting extreme and non-convergent views and ideas.

To stay as close as possible to the views of the study participants, interviews were undertaken in the local language, Tigrigna. In addition, the primary researcher conducted the translation and transcription of the interviews because he was originally from Tigray region and can speak the language and understand the culture. As indicated in the literature review, not much is known about children's outcomes and so nutritional outcomes in children were examined in the quantitative part of this study, where any conclusions made about children were based on objective measures and not only on their caregivers' reports. Hence, inclusion of data from caregivers and children was a novel feature of this study. In addition, this study collated and used nutritional program data that had not previously been analysed and, in a context, where such programs have been underevaluated because of feasibility concerns. Thus, the findings of this study will benefit nutritional programs in poor resource settings.

This study has also demonstrated the use and applicability of non-individual behaviour-based models in mixed methods research using quantitative and qualitative methods. It employed various models that extended our understanding about nutritional programs in HIV care settings more broadly. The use of the socioecological model enabled a comprehensive understanding of the challenges faced by nutritional programs in HIV care, identifying policy, community and institutional level issues such as access and program implementation and sociocultural factors. In addition, the socioecological model assisted in the demonstration and understanding of challenges to the nutritional program at multiple levels, and the ways in which these levels interacted to influence the nutritional program. This study also employed the social determinants of health model to interpret the effect of variables such as employment status, urban—rural difference and educational status on the nutritional program.

6.5.2 Limitations of the study

The initial plan was to include five hospitals and five primary health care centres to obtain a large dataset that would provide the current study with a stronger power. However, because of challenges related to feasibility, the research setting was reduced to three hospitals only. This reduction in study setting may have had an impact on other estimates of the quantitative findings, mainly death rates in the nutritional program for both adults and children and the relapse of undernutrition in children.

Limitations of the quantitative analysis include possibility of measurement error with misclassification of outcomes (for instance, recovered may have been classified as non-response or default or vice versa). However, such mis-classifications may be equally distributed among all outcomes and may have minimal effect on the current estimates. In addition, some baseline characteristics may not have been updated to the earliest possible time before enrolment in the nutritional program. There were missing values for some demographic and socioeconomic, immunological and clinical, nutritional and anthropometric characteristics but these were random and had no effect on estimations of the relationships between the independent and outcome variables.

The effects of small sample were reflected in this study in all nutritional outcomes, such as program incompleteness, non-response and relapse of undernutrition, as indicated by wide confidence intervals. Additionally, the effect of small sample size was particularly significant in the children's dataset as indicated by wide confidence intervals for the odds ratio estimates, and the inability to examine the determinants of relapse in children. Generally, the sample size was smaller than expected because of poor data management including lost cards and poor record handling in the sampled hospitals. In addition, records were collected manually and stored in hard copy which could easily be lost, and data tracking was difficult.

According to oral reports from people who were responsible for records management, records for people living with HIV who subsequently died were removed from the card room one year after their death, because there was inadequate space to store them. Consequently, the numbers of those who died during enrolment in the program were likely to be underestimated.

Moreover, there were 33 records excluded and these records may mainly be related to patients who fail to complete the nutritional program or die while in the nutritional program. The overall impact of these records may be underestimation of the magnitude of program incompleteness and death in the nutritional program.

The quantitative study used secondary data and the researcher was unable to follow up those who did not complete the program to see whether they had severe outcomes such as death, or whether they received alternative treatment elsewhere.

The qualitative study had a number of limitations:

- The setting or place of interview and characteristics of the interviewer may have influenced responses from the caregivers and adult participants, because some studies have suggested that patients say less or refrain from talking when interviews take place in a hospital (Tong, Sainsbury and Craig 2007). To minimize this, the researcher continuously reassured participants about the confidentiality of their interview as indicated in the ethical issues (section 3.6).
- 2) Translation can be intensive and time consuming. This may lead to the translator (in this case, the researcher) to bypass the rule of "translating everything" narrated by each participant. Such omissions, the use of abbreviations, and removing words that are believed to be unimportant may change the original meaning (Regmi, Naidoo and Pilkington 2010, p 19). Hence, some original meanings narrated by study participants may have been lost during the process of translation and transcription, thereby creating credibility issues. To address this issue, a transcription accuracy test was used to assist and improve the accuracy of translation and transcription. The investigator also speaks the language and understands the culture which assisted him to retain the original meaning.
- 3) Some participants were concerned about the presence of a recording device and were reluctant to speak in front of it. They were concerned that the interviews may be broadcast. This may have made them reluctant to be more critical of the program. To minimise this, continuous reassurance was delivered to all study participants about the confidentiality of the information provided. This helped respondents to express their views freely because they were continuously reassured that the audio records would not be used for other purposes than research. In addition, participants were reassured that participation or non-participation in interviews would not influence the service they received.

- 4) The quantitative orientation of the researcher might have influenced the qualitative data analysis and interpretation as indicated in the reflexivity section of the methodology (**section 3.5**). Furthermore, having a man interview women may have impeded female respondents through phenomena such as social desirability bias and hence they might not have expressed their internal feelings and experiences about the nutritional program. The researcher (interviewer) made maximum effort to be friendly and non-judgmental during interviews.
- 5) Having worked in the Ethiopian health system and being Ethiopian, the researcher may not have recognised and interpreted problems in the same way as an external investigator as stated in the reflexivity section in the methodology (section 3.5). While being Ethiopian had benefits for the researcher in terms of understanding the context, it may also have affected interpretation of the study as follows:
 - a) Some challenges in the nutritional program may have been considered as normal and usual because the researcher may be less sensitive to them.
 - b) Some health system related issues may not have been explored well in relation to the broad socioeconomic challenges. To address this, the supervisors of the researcher were all non-Ethiopian and had filled the possible gaps in this regard.
- 6) "Social desirability bias refers to the tendency of research subjects to choose responses they believe are more socially desirable or acceptable rather than choosing responses that are reflective of their true thoughts or feelings" (Grimm 2010, p 1). The researcher's position as a member of the Mekelle University's medical faculty staff interviewing health workers could have affected the results in terms of a social desirability bias. Health providers may be responded what the standards should be instead of the real practice and experience in the nutritional program as stated in section 3.5.
- 7) The acceptance rate in the qualitative interview (numbers of people who approached the researchers after being given the information by the health providers) seemed to be low and the possible reasons may be-a) the health providers may have not delivered accurate information about the study or may have forgotten to tell the patient during peak service time, b) health providers may have over reported the number of participants approached, c) participants may refuse to participate for a range of reasons including recent diagnosis and fear of stigma. Despite the low acceptance rate, it must be noted that data saturation was well achieved in this study.

6.6 Plan for dissemination of findings

Dissemination of research results is an essential component of the research process and it is key to consider the need of the target user of knowledge and its method of dissemination (<u>Gagnon 2011</u>; <u>Grimshaw et al. 2012</u>). Active and tailored dissemination of knowledge such as policy briefs and pamphlets are highly recommended for local policy makers to enhance better use of the evidence while publication in a reputable journal and presentation in local and international conferences is a passive knowledge dissemination mainly done for academic purpose. In addition, researchers can use more systematic ways to the adoption and use of their research results. (<u>Gagnon 2011</u>).

Results of this study will be disseminated in many ways for a wider applicability and use of the findings globally and nationally (Ethiopia). Findings of this study was disseminated internationally in four conferences (three oral and one poster presentation). The findings will also be published in reputable journal to ensure wider use of the research results and an electronic copy of the PhD thesis will be submitted to Flinders University library and it will be on an open access. Knowledge dissemination and evidence based decision making is a big problem in poor resource settings (Derman and Jaeger 2018). I intend to develop policy brief and make sure that my findings would feed into this. In addition, results of the study will be presented in national (Ethiopia) and local (Tigray region) conferences and will translate key messages to local language to enhance local use of the findings.

CHAPTER 7: CONCLUSION AND IMPLICATION

Introduction

The conclusions and implications are presented in the order as they appear in the main discussion to improve clarity. The points made are discussed and interpreted in the earlier discussion chapter.

7.1 Conclusion

This study presents a wide perspective on the various factors that contribute to the effectiveness of the nutritional program in HIV care settings. The nutritional program in Ethiopia achieved better results than seen in previous studies but program failure rate, particularly program incompleteness and non-response, was still high. Program relapse after nutritional recovery was also a common scenario, with a significant number of adults relapsing at least once.

A number of factors were associated with the lack of effectiveness of the nutritional program including individual characteristics such as urban residence, female gender, employed and working, enrolment in Lemlem Karl and Shul hospitals and old age (>60 years). Key factors contributing to relapse of undernutrition were lower level educational status and no membership of a community support group.

Clinical characteristics such as poorest clinical condition (advanced WHO stage and bedridden functional status), presence of opportunistic infection, and being on pre-ART at enrolment were also associated with poor program outcomes. Poorer nutritional status at enrolment, including severe acute undernutrition and anaemia, was also associated with lack of program effectiveness.

Participants had good knowledge about undernutrition, with many relating their weight loss to food factors. Furthermore, the motivation to enrol in the nutritional program was mainly related to weight loss, followed by recommendations from health providers, which both align with the aims of the nutritional program. Most participants only associated the nutritional program with nutritional support and not its broader elements such as nutritional counselling.

Weight loss was both an initial and ongoing motivation for enrolment and utilisation of the nutritional program. Furthermore, other factors such as the perception that the nutritional support was better than other foods and positive experiences with health providers enhanced continuous utilisation of the nutritional program.

Program related factors such as nutritional counselling, nutritional and health service factors were key in influencing utilisation of the nutritional program. For instance, despite the role of nutritional counselling in facilitating utilisation, issues such as its comprehensiveness, structure and consistency and the absence of training guidelines for health providers were identified as challenges. This was probably because the nutritional program had a main focus on the medical needs (treating undernutrition) of people living with HIV.

Other program related factors that were important for the utilisation of the nutritional program included issues related to the nutritional support. For example, mixing of the nutritional support with other foods to reduce side effects, diet boredom in some cases, and efforts to minimise frequency of visits to the health facility were common among study participants. Side effects related to the nutritional support constrained utilisation of the nutritional program mainly because participants disliked the salty and sugary taste of the nutritional support. Moreover, sharing of the nutritional support was common practice, mainly among adult females. Sharing was motivated by individual level factors such as lack of understanding about the nutritional program, and an attitude of sharing, supported by social and cultural norms, poverty and household food insecurity. While no adults or caregivers admitted selling the nutritional support, health providers reported this practice did occur.

Health service factors such as contextual differences between the study hospitals played an important role in program outcomes through differences in staffing, monitoring and supervision. In general, participant experiences suggested that the smaller hospitals were better able to work closely with patients. Other key health service factors across the program included quantity and quality of training of health providers in the nutritional program and lack of adequate service integration. In addition, barriers to accessing the program, including distance to the service and temporary movement of study participants to areas where there was no service coverage constrained utilisation of the nutritional program.

Broader health system factors such as funding, resource allocation and program design were important in influencing the outcomes and utilisation of the nutritional program. Concerns about sustainability of the nutritional program were highlighted, particularly the phasing out of NGO involvement and associated reduced funding. This reduction in funding was reported to have led to reduced monitoring, supervision and training of health providers and affected consistent supply of the nutritional support. Logistical issues with supply of the nutritional support were also highlighted.

Sociocultural and economic factors such as household food insecurity, poverty and poor livelihood, meaning of the nutritional support, religious fasting and stigma and discrimination were key contributors to nutritional program failure. For instance, household food insecurity was an essential challenge to the effectiveness of the nutritional program in many ways by influencing the motivation for enrolment, implementation of nutritional counselling and relapse. Other sociocultural issues highlighted were the cultural meaning of the nutritional support as a food, which was a source of concern mainly in adults because of its packaging, taste and preparation, and religious beliefs and practices around fasting.

Stigma and discrimination were identified as important barriers to the utilisation of the nutritional program. Because many adults and caregivers had not disclosed their positive HIV status, they were concerned that the nutritional program would reveal this and enhance stigma and discrimination through their need for more visits to the health facility and the visibility of the nutritional support (Plumpynut/Plumpysup) itself. These findings have important implications for future policy and these are discussed below:

7.2 Implications

7.2.1 Policy implications of the study

Broader policy implications

This study sheds light on the importance of comprehensive HIV policies that put nutrition at the centre of HIV care and support services. Issues related to food security policy that affect household food security should be taken into account in the design and implementation of nutritional policies in Ethiopia. This study calls for the nutritional program to create an opportunity to prevent undernutrition and foster nutritional wellbeing by linking people living with HIV with community nutrition and embracing nutrition specific (those that address the immediate determinants of undernutrition) and nutrition sensitive (those that address the underlying and systemic causes of undernutrition) policies.

The issues with the nutritional support identified in the study and the context of food security suggest the need for alternative ways of providing nutritional support. These might include locally produced nutritional support with local ingredients, or combining the provision of therapeutic food with other supports such as supplying households with food rations. Furthermore, the programmatic focus needs to encompass poverty reduction and livelihood programs as critical components of HIV care in resource-limited settings, to address food security issues and improve nutritional wellbeing of people living with HIV and prevent relapse. Moreover, a consideration needs to be given to household nutrition and family food security, particularly given that sharing was so common in households with children, because undernourished children need their full ration to recover.

Broader health system factors, such as decentralisation of the nutritional program in a similar way to ART services, are needed to improve access and enhance nutritional program effectiveness. Likewise, these services need to be funded through local and domestic funding to improve access and sustainability because funding and sustainability were major concerns. Given the finding about health service proximity, the location of health services requires special attention to improve access to the nutritional program.

NGOs are important partners in the Ethiopian health system but need to work more in relation to the local and national Ethiopian health priorities and health system issues while focusing on local capacity building. Nutritional programs in HIV care can be effective if implemented using targeted approaches with emphasis on special groups to address nutritional problems in HIV care in poor resource settings. The nutritional program needs to adopt special consideration in resource allocation by more broadly addressing gender and other gaps in vulnerability to food insecurity and poverty. For instance, there needs to be more emphasis in the nutritional program on women and individuals living in urban areas during enrolment, patient monitoring and follow up.

Broader programmatic implications

The study also provided insight into programmatic issues that need to be addressed. In particular, attention should be directed to the enrolment and graduation criteria. For instance, household socioeconomic status should be considered in enrolment and the program length extended if it is required. Graduation criteria should take into account long term household food security, not just the acute treatment of undernutrition.

Relapse of undernutrition after nutritional recovery was challenging the effectiveness of the nutritional program. Hence, livelihood programs should be incorporated to prevent relapse of undernutrition. Different models of livelihood programs targeting people living with HIV from rural and urban areas need to be in place to improve the effectiveness and benefits of the nutritional program. Evidence suggests multiple strategies are needed to address food insecurity and improve nutritional outcomes for people living in rural and urban areas. For instance, microenterprise training with the assistance of microfinance for people living in urban areas and training of small scale agriculture and farming techniques for people from rural areas could improve the nutritional wellbeing of people living with HIV (Mensah, Okyere and Doku 2015; Yager, Kadiyala and Weiser 2011).

There is strong evidence demonstrating the importance of peer education and counselling in improving ART adherence and this can be applicable to nutritional counselling in HIV care settings (Kanters et al. 2016; Uwimana et al. 2012). Reorientation of the nutritional counselling towards a holistic and comprehensive approach to enhance maintenance of weight or good nutrition is recommended. The nutritional counselling should be holistic and goal oriented and move beyond the nutritional supplement. There are human resource problems within the nutritional program and thus task shifting needs to be considered. Services such as nutritional and dietary assessment, nutritional counselling and education, anthropometric measurement and other nutritional and dietary screening could be performed by trained people living with HIV. According to Okyere, Mwanri and Ward (2017), task shifting has the potential to fill gaps and shortage in the supply of health workers in developing countries. Shifting of some tasks to trained people living with HIV may help to address the burden on health providers.

Program implementation and operation

Health providers should emphasise the importance of trust in the utilisation of health services particularly in HIV care to create and improve the supportive environment in health facilities and in turn improve utilisation of the nutritional program. Moreover, many studies demonstrated that quality of service is crucial in improving health service utilisation in HIV care (Dansereau et al. 2015; Pilgrim et al. 2018). Improving quality of service to improve utilisation, efficiency and effectiveness of HIV care and nutritional programs is vital. For instance, concerns about the integration, skill and experience of health providers should be addressed. In addition, standardised training is needed to improve skills and experience of health providers, with a special focus on monitoring and follow up of people living with HIV enrolled in the nutritional program. To support monitoring and evaluation, better data management systems are required, particularly the use of comprehensive electronic data systems to facilitate timely analysis of outcomes and identification of programmatic issues.

The sociocultural factors identified in this study have not been taken into consideration sufficiently in the design of nutritional programs. Hence, to improve effectiveness of the programs these factors need to be incorporated. For example, involving local and regional religious leaders in the design and implementation of nutritional programs is crucial for improving utilisation and addressing stigma and discrimination. In addition, program design and implementation of the nutritional program in HIV care should be contextualised to the local food culture through some of the measures suggested above, including using local ingredients (Bahwere et al. 2011; Frank et al. 2013) and improving taste.

Many studies demonstrated the importance of community based HIV support services in improving clinical outcome by enhancing adherence to ART and facilitating utilisation of HIV service (<u>Kabore et al. 2010</u>; <u>Wouters et al. 2012</u>). Community support groups in the current study was also found to be helpful in improving the effectiveness of the nutritional program in HIV care. For this reason, community support groups should strengthen, and adequate funding should be provided.

In addition, stigma reduction strategies such as peer education, involvement of religious leaders and community support group should be considered.

7.2.2 Research implications of the study

While this study identified determinants of nutritional outcomes and the barriers to and facilitators of nutritional programs among adults and caregivers, children were not directly involved. Further research could examine children's perspectives through a range of ethical and appropriate means – for example, art work or food diaries. Children have the right to participate in research as research subjects but they need special protection from potential harms in research (Allmark 2002; Skelton 2008). The principles of research ethics for children are similar to those for adults, but children are particularly vulnerable to coercion and other unethical practice because of their lack of complete understanding and openness on many issues (Davidson and O'Brien 2009). Use of innovative approaches which are responsive to children's skills such as drawings or diaries are becoming popular research approaches (Punch 2002) that can be used to further investigate nutritional programs in HIV care settings for children living with HIV. Because of the small number records for children, this study was unable to investigate the determinants of nutritional outcomes, mainly relapse of undernutrition, in children living with HIV and this should be an area of investigation for future studies with larger sample sizes.

According to findings of this study, supply management of the nutritional support had an impact on the nutritional program outcomes, but these supply issues were not comprehensively examined. Future research is needed to investigate supply management issues in further detail.

Nutritional counselling may be delivered more effectively and better accepted if peer educators are involved but this needs further research and investigation to gain an in-depth understanding of the experiences of peer educators and program participants.

Further research is also needed to investigate how the nutritional program functions in primary health care centres and health posts compared with hospitals, to examine potential improvements to access by decentralising the nutritional program to the lowest level health services.

Additional research regarding poverty oriented innovative nutritional programs in HIV care setting such as locally and contextually sound livelihood programs might also help to further address nutritional issues of people living with HIV and advance knowledge regarding nutritional program in special groups.

7.2.3 Future applications of the socioecological model in this area

The SEM has never been used to inform studies regarding nutritional programs in HIV care. This conceptual model yielded a comprehensive view of the challenges of the nutritional program in HIV care settings such as health system, sociocultural and health service factors that shaped individual behaviour in the outcomes and utilisation of the nutritional program in HIV care setting. The current study has provided empirical evidence that supports the future use and applicability of the SEM to evaluate and design nutritional programs in HIV care and extended the knowledge base for using the SEM in the evaluation of nutritional programs in special groups. Use of the SEM has deepened an understanding about the challenges of the nutritional program in HIV care and can be used as a foundation to design strategies to improve the effectiveness of nutritional programs in HIV care. The model can also be applicable in HIV related and other studies to explore various factors that interplay at various levels. The SDH model was also used to supplement the SEM and can be applied to evaluate nutritional programs from the perspective of equity.

7.2.4 Final statement

This study identified the challenges of the nutritional program by providing a comprehensive evaluation of the individual, inter-individual, institutional, community and policy level challenges which may assist the reorientation of the nutritional programs in HIV care setting from a medicalised approach to more holistic and poverty oriented programs in Ethiopia and other low resource settings. It is hoped that this knowledge will assist in improving the effectiveness of nutritional programs in HIV care by informing policy, planning and implementation of nutritional care in the context of HIV and AIDS in low resource settings in general and Ethiopia in particular.

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APPENDICES

Appendix A: Quantitative data collection checklists

Adult checklists

Flinders University, Faculty of Medicine, Nursing and Health Sciences, School of medicine, Southgate Institute for Health Society and Equity

This checklist will be used to abstract data about sociodemographic, clinical, immunological, nutritional and anthropometric characteristics of adult HIV patients on food by prescription program in selected hospitals of Tigray region, Northern Ethiopia. Circle the responses for each patient's characteristics in the table below as indicated in the registration book of food by prescription and the intake form of HIV care/ART clinic.

Data collector name	-Signature	Date	
Patient medical registration number (MRN)		antiretroviral (ART) unique	number if on
ART RUTF unique number	Name of	hospital	

I. Demographic and Socioeconomic variables

S.NO	QUESTION	RESPONSE
101	Date of admission to nutritional program	
102	Date of exit/discharge from nutritional program dd/mm/yy	
103	What is age of the patient in years? dd/mm/yy	year
104	What is the sex of the patient?	1. Male 2. Female
105	Patient's place of residence	1. Urban 2. Rural
106	What is the marital status of the patient	 Never married Married (inc. defacto) Separated Divorced Widow/widower
107	What is the Educational status of the patient	 No education Primary Secondary Tertiary

108	Religion of the patient	 Muslim Orthodox Christian Protestant Catholic Others, specify
109	Employment of the patient	 Working full time Working part time Employed but not working due to ill health Unemployed Not documented
110	Husband and wife have children	1. Yes 2. No
111	Number of people in the house hold?	individuals
112	Community support /HIV support groups	1. Yes 2. No
113	Does anyone know about your HIV status?	1. Yes 2. No

II. Clinical and Immunological Variables

S.NO	QUESTION	RESPONSE
201	Baseline functional status (functional status at or before admission to nutritional program)	 Working Ambulatory Bedridden
202	Baseline WHO clinical stage (WHO stage at or before admission to nutritional program)	 WHO stage 1 WHO stage 2 WHO stage 3 WHO stage 4
203	What was the baseline CD4 count before or during enrollment to the nutritional program?	() μl/mm³
204	CD4 count at or after discharge from nutritional program	ul/mm³
205	What was the Baseline Hgb. Level at admission/before to nutritional program	() g/dl
206	What was the ART status during enrollment to nutritional program?	On Pre HAART Receiving HAART
207	ART regime at enrolment	1. NNRT 2 NRT 3. PI 4. NNRT+NRT 5. NRT +PI 6. NNRT+NRT
208	If the patient receiving HAART, for how long he/she was receiving HAART (Duration) at enrolment to FBP	() months
209	Does the patient on Cotrimoxazole prophylaxes before or during admission to FBP?	1. Yes 2. No
210	Did the patient have any opportunistic infection or sign of sever disease during admission?	1. Yes 2. No
211	If yes in above (Q 210), what was that?	 TB TB and other Others specify

III. Nutritional and anthropometric related variables

S.N	QUESTION	RESPONSE
0		
301	Baseline Weight during admission to nutritional program	() Kg
302	Baseline Height during admission to nutritional program	() Cm
303	Baseline BMI at admission to nutritional program) Kg/m²
304	Weight at exit /discharge) Kg
305	Height at exit /discharge from nutritional program	
306	BMI at exit /discharge from nutritional program) Kg/m²
307	What is the nutritional status during enrollment to	Mild malnutrition Madagate acute malnutrition
	nutritional program?	 Moderate acute malnutrition Sever acute malnutrition
308	How many prescribed RUTF/RUSF per day the patient	() sachets
	was taking?	,
	9	
309	What was the duration of stay on the RUTF program in	
	Weeks?	
		() Weeks
310	Did appetite test done during enrolment to the nutrition	1. Yes
310		2. No
	program?	
311	If yes, what was the appetite test result?	1. Good
	, , жероше состобым.	2. Poor
312	What was the subsequent weights gain?	1. Good
	-	2. Poor
313	What was the treatment outcome (at exist)?	Graduated/recovered
		 Non-respondent Defaulted
		Loss to follow up
		5. Death
		6. Transferred out
314	Did the patients relapsed after nutritional recovery	1. Yes 2. No
315	If yes to Q314, date, month and year of first time recovery	
	after enrolment to the nutritional program (dd/mm/yy)	

316	If yes	to	Q314,	date,	month	and	year	of	
	relapse(dd/m	m/yy)						

Children checklists

Flinders University, Faculty of medicine, nursing and Health Sciences, School of medicine, Southgate for Health Society and Equity

This checklist will be used to abstract data about sociodemographic, clinical and nutritional
characteristics of HIV patients on food by prescription in selected hospitals in Tigray region,
Northern Ethiopia. Circle the responses for each patient's characteristics in the table below as
indicated in the registration book of food by prescription and the intake form of HIV care/ART clinic.
Data collector nameDateDate
Patient Medical Registration Number (MRN) ART unique ID No if on ART
RUTF unique numberName of hospital

IV. Demographic and Socioeconomic variables

S.N	QUESTION	RESPONSE	Skip
0			
101	Date of admission to nutritional program		
	(dd/mm/yy)		
102	Date of exit/discharge from nutritional		
	program (dd/mm/yy)		
103	What is age of the child in years?	year	
104	What is the sex of the child?	1. Male	
104	what is the sex of the child?	1. Male	
		2. Female	
105	Child patient's place of residence	1.Urban	
		2. Rural	
106	Child lives with at enrolment to FBP?	1. Parents	
		2. Guardian3. In orphanage	
		4. Grand parents	lf
		5. Siblings	other
			than 1
			to 108
107	If the child lives with parents?	Mother and father live together	
		Divorced Widowed	
		Vidowed Single parent father	
		5. Single parent mother	

108	Mother alive?	1. Yes	If 2 to
		2. No	110
109	If mother alive, occupation of mother?	1. Working full time	
		2. Working part time	
		3. Employed but not working due to ill health	
		4. Unemployed	
440	Father allows O	5. Not documented	If O 4-
110	Father alive?	1. Yes 2. No	If 2 to
		2. 110	112
111	If father alive convention of father?	4 Moulting full time	
111	If father alive, occupation of father?	Working full time Working part time	
		3. Employed but not working due to ill	
		health 4. Unemployed	
		Onemployed Not documented	
112	Child's birth order		
113	If child is living with guardian, relation to	1. Relative	
	the child?	2. Not relative	
114	Guardian's acceptance of the child?	Willing to accept the child Not willing to accept the child	
4.4.5		2. Not willing to accept the child	
115	If the child lives in orphanage, does the	1. Yes 2. No	
	orphanage has its own health facility?	2. 140	
440	Dood the shild attend as lead "	4 Vaa	
116	Does the child attend school (for	1. Yes 2. No	
	children>5 years)	2. 110	
117	If No to Q 116, reason for not attending	1. Too young	
	school.	2. Lack of fund	
		3. Others, specify	

V. Immunological and Clinical Variables

S.NO	QUESTION	RESPONSE
201	What was the WHO clinical stage at enrolment to nutritional program?	1. WHO stage 1 2. WHO stage 2 3. WHO stage 3 4. WHO stage 4

202	What was the CD4 count during enrollment		
	to the nutritional program?	() μl/mm³	
203	What was CD4 count at discharge from nutritional program?	ul/mm ³	
204	What was the Hgb level at admission to the nutritional program?	() g/dl	
205	What was the ART status during enrollment to nutritional program?	On pre-HAART Receiving ART	
206	If the patient is receiving HAART during enrolment to nutritional program, for how long has he/she received HAART (Duration) at the time of admission to nutritional program?	() months	
207	Does the child been on cotrimoxazole prophylaxes during admission to FBP?	1. Yes 2. No	
208	Did the child have any opportunistic infection or sign of sever disease during admission to nutritional program?	1. Yes 2. No	
209	If yes, in the above (Q 208), what was that?	1. TB 2. TB and other 3. Others, specify	
210	ART treatment eligibility	 Eligible because of WHO clinical stage only Eligible because of CD4% count/TLC only Eligible based on both CD4% and WHO clinical stage Eligible because of other reasons Not eligible 	

VI. Nutritional and anthropometric related variables

S.N	QUESTION	RESPONSE
0		

301	Weight during admission to nutritional program	() Kg
302	Height during admission to nutritional program	() Cm
303	BMI at admission to nutritional program.) Kg/m²
304	MUAC at admission to nutritional program.	() Cm
305	Weight for height at admission to nutritional program	
306	Weight at exit /discharge.) Kg
307	Height at exit /discharge from nutritional program.	() cm
308	BMI at exit /discharge from nutritional program.) Kg/m ²
309	MUAC at exit from nutritional program	
310	What is the nutrition status during enrollment?	Mild acute malnutrition Moderate acute malnutrition Sever acute malnutrition
311	How many prescribed RUTF per day the patient was taking?	() sachets
312	What was the duration of stay on the nutritional program in Weeks	() Weeks
313	Did appetite test done during enrolment to RUTF?	1. Yes 2. No
314	What was the outcome of the appetite test	1. Good 2. Poor
315	What was the subsequent weights gain?	1. Good 2. Poor

316	What was the nutritional outcome (at exist)	 Graduated/recovered Non-responder Defaulted Loss to follow up Death Transferred out
317	Did the patients relapsed after nutritional recovery	1. Yes 2. No
318	If yes to Q317, date, month and year of first time recovery after enrolment to the nutritional program	
319	If yes to Q317, date, month and year of relapse	

Appendix B: Interview guide

Adults living with HIV

Sociodemographic characteristics of study participants				
S.N <u>o</u>	Questions	Code and category		
Q101	How old are you?	Years		
Q102	What is your religion?	 Orthodox Muslim Protestant Catholic Others specify 		
Q103	What is your ethnicity	 Tigray Amhara Oromo Gurage Others, specify 		
Q104	Are you currently married or living together with a man/woman as if married	 Never married Yes, currently married Yes, living with a man/woman but not married Widow Divorced Others: 		
Q105	Who lives with you in your household and how many (including yourself)?	4		
Q106	Have you attended formal school?	1.Yes 2. No		
Q107	If yes to Q 106 What is the highest grade you completed?	 Primary Secondary Tertiary and above 		
Q108	What is your current employment status?	Employed Not employed Others specify		
Q109	What is your household's average monthly income? (it means your and your spouse's income combined)	ETB		

110	Average distance to reach the health facility	Hours'
	you receive FBP service?	
111	How long have you been in the program?	Months

1. Can you tell me a bit about your HIV condition, family and the services you get for your HIV?

Probing questions

- How long has it been since your diagnosis?
- Are there other family members living with you who have HIV?
- What services/treatments are you getting for your HIV? (**Probe**: ART, nutritional assessment, nutritional counselling and provision of therapeutic/supplementary food?)
- 2. Okay my interest/study is around the food, your weight and nutrition problems that some HIV patients have. Can we talk a bit about how and why you got involved in the nutrition program?

Probing questions

- Can you recall why they recommended the program to you?
- Was your weight and nutritional status a concern to you?
- Can you tell me the reasons that you are thin/malnourished?
- How do you think your life situation like access to food and affordability attributed to poor nutritional status?
- Can we talk a bit about the reasons people or you need such therapeutic/supplementary food?
- 3. What has been the best services you received from this clinic in relation to the weight and nutrition problems so far? Why?
- 4. Have your nutrition condition and weight improved since you have been involved in the program? Why do you think so? If not, what are the key reasons?
- 5. About the food provided to you, do you use it as recommended by the health providers

Probing questions

- How you consume it
- Can you tell me about the taste, ration size, is it different from what you eat at home?
- When you receive the supplementary/therapeutic food, whom do you though is the other people you share with?
- Have you ever think of stopping using it (what are your reasons)?
- How you transport it to your home
- 6. Now, I will ask you about the nutritional counselling you get in the FBP clinic.

Probing questions

- How helpful is the nutritional counselling to maintain your weight?
- How does the nutritional counselling given here benefited you in relation to the supplementary/therapeutic food?
- Do you think the health provider considers your household or life conditions when providing counselling?
- Can you describe me a typical counselling session?
- Have the health providers explained to you how and when to use the supplementary/therapeutic food? Are you given the chance to ask questions or the challenges you have?
- 7. Ok, let's talk about cultural, religious and others issues that might affect your use of the supplementary /therapeutic food

Probing questions

- Are there particular beliefs about food and malnutrition in your community? Do these beliefs influence you how you use or think about the food by prescription program?
- Who knows in your family, friends and neighbours that you are taking the supplementary or therapeutic food?
- Can knowledge by your neighbour or friends affect your continued use of the supplementary or therapeutic food? (Why?), Its impact to access social services?
- Do you have any problem in taking the food in front of your family, friends or neighbours, etc.?
- Can you consume the food anytime or are there times where you can't take it? (why)
- 8. Does your use of the therapeutic food relate to your HIV treatment? (Why and how?)
- 9. Have you been in the program before and what is your previous history?
 - Did you recovered before and enter to the program again?
- 10. Have you had any difficulties being put at the program? How did you overcome them or how would you supported to overcome them?
 - How do you think the program can be improved?

Caregivers of children living with HIV

Socio demographic characteristics of the mother				
S.N <u>o</u>	Questions	Code and category		
Q101	How old are you?	Years		
Q102	What is your religion?	 Orthodox Muslim Protestant Catholic Others specify 		
Q103	What is your ethnicity?	 Tigray Amhara Oromo Gurage Others, specify 		
Q104	What is your marital status?	 Never married Married Widow Divorced Others: 		
Q105	Who lives in your household and how many including yourself?			
Q106	Have you attended formal education?	1. Yes 2. No		
Q107	If yes to Q 105, what is the highest grade you completed?	 Primary Secondary Tertiary and above 		
Q108	What is your current occupation?	Employed Not employed		
Q109	What is the Average monthly household income of your family?	ETB		
Q110	Are you currently married or living together with a man/woman as if married?	 Never married Married Widow Divorced Others, specify 		
Q111	Average distance to reach health facility	hours		

Q112	How long has been your child in the nutritional program	Months
	Characteristics of the child	
Q 113	Age of the child	Years
Q 114	Sex of the child	1. Male 2. Female
Q 115	If the child is 7 years and older, does he/she attend school?	1. Yes 2. No

1. Can you tell me a bit about your child's HIV condition, family and the services your child get in this clinic?

Probing questions

- What is your relationship with the child?
- When was your child's HIV status been confirmed?
- Does anyone else has HIV in you?
- What service /treatments is your child getting in this clinic (HIV clinic)? (Probe: ART, nutritional assessment, nutritional counselling and provision of therapeutic/supplementary food?)
- 2. Okay my interest/study is around food, the thinness and nutrition problem that some children with HIV have. Can we talk a bit about how and why you get involved in the food program?

Probing questions

- How important is nutrition in general and the therapeutic /supplementary food in general?child? (**Probe**: what do you think makes it special when it comes to children with HIV?)
- Are there community myths about malnourished children and how does this affect to feed the therapeutic/supplementary food?
- Can you tell me the reasons that your child is thin/malnourished?
- Can you recall why they recommended the program to your child?
- Can we talk a bit about how your come to the enrol in the therapeutic/supplementary food?
- 3. What has been the best services you received from this clinic in relation to the weight and nutrition problem so far? Why?
- 4. Have the nutrition condition and weight of your child improved since you have been involved in the program? Why do you think so? If not, what are the key reasons?
- 5. About the food provided to your child, do you use it as recommended by the health providers

Probing questions

- Did your child like to eat the food? How enough is the ration size? Is it different from what your child eats at home?
- What are all the ways you feed the therapeutic/supplementary food?
- When your child receive the supplementary food, who are there other people they share with? Can you tell me the reasons for sharing the food?
- Have you ever thought of stop using the program (if yes, what are your reasons)?
- How do you transport it from health facility to your home?

Health providers

Socio demographic characteristics of study participants				
S.N <u>o</u>	Questions	Code and category		
Q101	How old are you?	Years		
Q102	Gender	Male Female		
Q102	What is your religion?	1. Orthodox 2. Muslim 3. Protestant 4. Catholic 99.Others specify		
Q103	What is your ethnicity?	 Tigray Amhara Oromo Gurage Others, specify 		
Q104	What is the highest educational level attained?	1. Diploma 2. BSc degree 3. Masters 4. Others		
Q105	How long has it been since you start working in your current profession	years		
Q106	What is your position in TRHB			
Q107	How long has it been since you start working in your current position?	years		

1. Can you tell me a bit about the services offered to HIV patients in this clinic?

Probing questions

- Chronic HIV care
- ART
- Nutritional assessment
- Nutritional support
- Nutritional counselling
- 2. Can you describe me the specific activities of the nutritional program?
- 3. Ok, I am interested with the nutritional program given to HIV patients (specifically children and adults). What do you think is about the patients' attitude and perception about the FBP?

Probing questions

- How and to what extent did patients use the food as prescribed?
- What is the response of the patients to the therapeutic /supplementary food? (How many improve? For those failing to improve, what are the reasons for non-response and default?
 - ✓ Adults
 - ✓ Children
 - What mechanisms did you use to ensure that patients are using the prescribed food as recommended and how compliant are the patients to the food?
 - Are there misuses of the prescribed food by patients (adult and children), what are these misuses and reasons for misuses?
- 4. In your view, what health service related issues negatively or positively affect the use of the nutritional program?

Probing questions

- What is the level of integration of the nutritional program and other HIV services (appointment date? Service provision, use of the same person, time and space for all the HIV and nutritional program services?
- Are there human power and supply related issues in the nutritional program and how does those influence the nutritional recovery?
- How did beneficiaries of the nutritional program perceive about the supplementary/therapeutic food? (Food to fulfil dietary needs, medicinal food or food to be shared among family members?)
- When do patients discontinue from the therapeutic food in the course of the nutritional therapy (Probe: why?)
- 5. How complaints are beneficiaries of the nutritional program to the nutritional counselling? **Probing questions**

- Why do some patients fail to comply and others do?
- Can you tell me the mechanisms patients use the nutritional support?
- Have you come across any refusal of the nutritional support? (Why?)
- 6. How frequent and to what extent is the nutritional counselling? (Mention some general points about the counselling)?
- 7. Community related issues that influence use of the nutritional program (Adult and children HIV patients).

Probing questions

- Perceived stigma, food practice, culture, religion (fasting).
- Do you think that patients consumption of the therapeutic /supplementary food affects their interaction with community they live in (neighbours, friends) (how?)
- 8. As health providers, what concerns surround the HIV care and support service in general and the nutritional program in particular? (Adult and children).

Probing questions

- Adherence to ART and pre-ART service and its impact on the nutritional program?
- Cultural and religious appropriateness of the therapeutic /supplementary food
- About the taste, ration size, packaging and transportation
- 9. Now, let's talk about the challenges of the nutritional program, what challenges and success are there about the nutritional program? In general (adult and children in particular).

Probing questions

- Services or program related challenges to the FBP program (**Probe**: treatment duration, enrolment, exit criteria, the food product, patients)
- What needs improvement? Possible recommendations to improve nutritional recovery, nutritional status and overall quality of life of adult and children HIV patients.

Program managers

1. Can you tell me a bit about the services you offered in the HIV care program?

Probing questions

- To the clinics in the health facilities
- To the health providers
- To the patients/clients
- 2. Can you describe me the specific activities of the nutrition coordinating office of the nutritional program?
 - At program level
 - At facility level
 - Individual client
- 3. Ok, I am interested with the nutritional program given to HIV patients (specifically children and adults). How do you

Probing questions

- How do you monitor, supervise and coordinate the nutritional program
- 4. In your view, what health service related issues negatively or positively affect the use of the nutritional program?

Probing questions

- What is the level of integration of the nutritional program and other HIV services at program /regional level?
- Reporting and monitoring
- Issues related with the health facility.
- Program related issues
- 5. How did the nutrition coordinating office work to make nutritional counselling as a core component of the nutritional program?

Probing questions

- To patients
- To health facilities
- 6. What community related issues influence the nutritional program?

Probing questions

- Stigma
- Fasting
- 7. What do you think is the role of the nutritional program in improving retention of HIV patients in the HIV care service? (Patients adherence to the care, ART, default and retention in care)
- 8. As health program manager, what concerns surround the HIV care and support service in general and the nutritional program in particular? (Adult and children).

Probing questions

Sustainability issue

- How continuous and linked is the nutritional program
- 9. Now, let's talk about the challenges of the nutritional program, what challenges and success are there about the nutritional program? In general (adult and children in particular).

Probing questions

- Services or program related challenges to the FBP program (**Probe**: health system related, and patient related).
- What needs improvement? Possible recommendations to improve the nutritional program and quality of life of HIV patients.

Appendix C: Ethics Approval

Flinders University- Australia



27 January 2016

Mrs Andrea Fiegert

Executive Officer, <u>Social and Behavioural</u> <u>Research Ethics Committee</u>

Room B6, Basement, Union Building GPO Box 2100 Adelaide SA 5001 Telephone +61 8 8201 3116 human.researchethics@flinders.edu.au Facsimile +61 8 8201 2035 http://www.flinders.edu.au/research

Dear Fisaha,

The Chair of the <u>Social and Behavioural Research Ethics Committee (SBREC)</u> at Flinders University considered your response to conditional approval out of session and your project has now been granted final ethics approval. This means that you now have approval to commence your research. Your ethics final approval notice can be found below.

FINAL APPROVAL NOTICE

Project No.:	7	7118			
Project Title: Food by prescription in HIV patients in Tigray region Ethiopia: an assessment of outcomes and determinants					
Principal Researcher:		Mr Fisaha Te	esfa	у	
Email:		tesf0008@flinders.edu.au			
Approval Date:	27 Jar	nuary 2016		Ethics Approval Expiry Date:	23 February 2019

Mekelle University- Ethiopia

Mekelle University College of Health Sciences Health Research Ethics Review Committee (HRERC)

To:

Fisaha Haile Tesfay

Principal Investigator

Mekelle

Date:

March, 29, 2016

Notification of EXPEDITED Approval

ERC 06211/2016

Protocol: Food by prescription in HIV patients in Tigray region, Ethiopia: An assessment of outcomes and determinants

Dear PI:

This is your notification that your above referenced study has received **EXPEDITED APPROVAL** on 29/3/2016. This ethics review approval will expire on 28/3/2017.

The research study cited above has been reviewed and it has been determined that it meets the criteria for expedited review. The HRERC will be apprised of this decision at its monthly meeting.

Any reportable events (serious adverse events, breaches of confidentiality, protocol deviation or protocol violations) or issues resulting from this study should be reported immediately to the HRERC. Any amendments (changes to any portion of this research protocol including but not limited to protocol or informed consent changes) must have HRERC approval before being implemented.

All correspondences and inquires concerning this research protocol must include the ERC number, the name of the PI and the protocol title.

Sincerely,

CC:

Dean, College of Health Sciences **Mekelle University**

Commencing health research without approval is unethical!



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The Government of the National Regional State of Tigray, Bureau of Health

Re.No 387/1418/08

Date 19/07/08

To Mekelle General Hospital

To Lemlemkarl General Hospital

To Sihul General Hospital

Subject:- Letter of Permission for Data Access for Research

Dear Sir/Madam,

We are writing this letter of permission in reference to the support letter submitted to our bureau from Mekelle University College of Health Sciences dated 25/03/2016 through reference No. CHS/690/PH-08 on accessing data from Public Hospitals to the Principal Investigator Mr. Fisaha Haile Tesfay for his PhD Dissertation, entitled "Food by Prescription in HIV Patients in Tigray Region, Ethiopia."

Hence, this letter of permission is kindly given to Mr. Fisaha Haile Tesfay to collect any imperative data that would value add to his study in which would contribute great input for the policy makers aiming at strengthening the health system of the region and the country as well.

Best regards

Abrahim Hassen Research, Projects and International Relations, Coordinator

CC:

To Flindres University, SBREC Adelaide, South Australia

To Fisaha Haile Tesfay

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 4.ክስ 251-034-440-88-30 Fax ኢ.መይል tigrayhealth@telecom.net.et E-mail መቐለ ትግራይ ኢትዮጵያ Mekelle, Tigray, Ethiopia

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Tigray Bureau of Health

Mekelle Hospital
Date 29/3/20/6

መቐለ ሆፒታል RNo <u>1195 1 1/12 | 20 | 6</u>

To: ART case team. Mekelle Hospital Mekelle

Subject: Permission letter for data access

Mr Fisaha Haile Tesfay is a staff member of the school of Public Health, Mekelle University pursuing his PhD study in Flinders University, Australia. He will collect data related to HIV and food by prescription for his PhD project entitled "Food by prescription in HIV patients in Tigray region, Ethiopia: an assessment of outcomes and determinants" in our hospital. It involves extraction of secondary data from the food by prescription and ART registers in our hospital as well as qualitative interview with adult HIV patients, care givers of children HIV patients and the nutrition program staffs (health providers and program managers) which will contribute to improve the HIV care and support service.

Hence, this letter of permission is granted to Mr Fisaha Haile Tesfay to collect secondary data from the ART and food by prescription registers in our hospital as well as qualitative interview with adult HIV patients, caregivers of children HIV patients, and program staffs (health providers and program managers) in our hospital. In addition, please provide him with all the necessary support during his data collection process in your case team.

Kind regards

Hailekiros Embaye Metron

C.c

- Mr Fisaha Haile Tesfay

- CEO Mekelle Hospital

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To: ART case team, Shul Hospital

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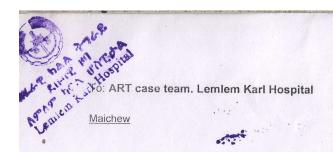
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Kind regards

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Noi- 3178/03/098 daet- 3/9/08

Subject: Permission letter for data access

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