

FOOD SECURITY AND ANTIRETROVIRAL THERAPY ADHERENCE AMONG PEOPLE
LIVING WITH HIV IN LUNDAZI DISTRICT, ZAMBIA: A PILOT STUDY

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ABSTRACT

Rainier DeVera Masa: Food Security and Antiretroviral Therapy Adherence
among People Living with HIV in Lundazi District, Zambia: A Pilot Study
(Under the direction of Gina A.N. Chowa)

Food security, or adequate access to food at all times, is critical to the health and well-being of people living with HIV (PLHIV). Research has shown that food insecurity is associated with suboptimal adherence to antiretroviral therapy (ART). Nonadherence, in turn, predicts adverse health outcomes, including higher risk of mortality. However, evidence remains limited on the prevalence, correlates and effects of food insecurity on treatment adherence, as well as appropriate strategies to improve food security in rural and resource-limited settings. This dissertation aims to: 1) expand the literature on food insecurity and ART adherence in resource-limited settings, particularly in rural communities; and 2) examine the effectiveness of an income-generating strategy to increase food security and treatment adherence among PLHIV in Lundazi District, Eastern Province, Zambia. The study sample included 101 PLHIV who were attending two health facilities in Lundazi District and participating in a pilot integrated HIV and livelihood program. Consistent with prior research, food insecurity was highly prevalent among the study sample. Ninety-three and 95 percent of the sample were food insecure at baseline and follow-up, respectively. In addition, at least 70% of the sample was severely food-insecure at both time points. In this rural sample of PLHIV, food insecurity was predicted by lack of economic security in the household. Lower income, fewer assets, and having debts were significantly associated with food insecurity. Results also indicated an inverse, albeit not statistically significant, association between food insecurity and treatment adherence. Food-insecure PLHIV were less likely to achieve optimal treatment adherence contrasted with food-secure PLHIV. Finally, participation in a livelihood program contributed to statistically

significant increase in food security, as well as positive effect on treatment adherence. Findings suggest that food security can be improved using a promising intervention that targets underlying social and economic determinants of food insecurity among PLHIV. Implications of findings for social work policy, practice, and research, as well as key study limitations, are discussed.

In loving memory of my father, *Generoso Montecillo Masa*.

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LIST OF ABBREVIATIONS

AIDS	acquired immune deficiency syndrome
AMPATH	Academic Model Providing Access to Healthcare
AOR	adjusted odds ratio
ART	antiretroviral therapy
ARV	antiretroviral
BE	backward elimination
BMI	body mass index
CD4	helper T-cell of the human immune system
CFALP	combination food assistance and livelihood program
CoRT	conservation of resources theory
CSO	Central Statistical Office, Zambia
FA	food assistance
FANTA	Food and Nutrition Technical Assistance Project
FAO	Food and Agriculture Organization
FPI	Family Preservation Initiative
HFIAS	household food insecurity access scale
HFIAP	household food insecurity access prevalence
HIV	human immunodeficiency virus
HBM	health belief model
IHLP	integrated HIV and livelihood program
IMSM	information-motivation-strategy model
ITT	intention-to-treat
LDH	Lundazi District Hospital
LMH	Lumezi Mission Hospital

MI/MICE	multiple imputation (by chained equations)
MoH	Ministry of Health, Zambia
MPR	medication possession ratio
MTP	memberships theory of poverty
NAC	National AIDS Council, Zambia
OLS	ordinary least squares
PLHIV	people living with HIV
RUTF	ready-to-use therapeutic food
SCT	social cognitive theory
SSA	sub-Saharan Africa
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VAS	visual analog scale
WFP	United Nations World Food Programme
WHO	World Health Organization
ZANACO	Zambia National Commercial Bank
ZMK/ZMW/K	Zambian kwacha

INTRODUCTION

Food insecurity, which is defined as the inability of individuals and households to access and maintain at all times adequate, safe, and nutritious food that meet dietary needs (Food and Agriculture Organization [FAO], 1996), remains a global challenge. In sub-Saharan Africa (SSA), the HIV epidemic has exacerbated the already significant social and economic problems caused by food insecurity and poverty. The interaction of food insecurity and HIV creates a cycle, with food insecurity increasing risk to HIV exposure and infection, and HIV in turn heightening vulnerability to food insecurity by limiting household income and food production (Gillespie & Kadiyala, 2005; Weiser et al., 2011). Further, food insecurity increases risk of adverse health outcomes for people living with HIV (PLHIV), including heightened risk of mortality (Koethe et al., 2013; Weiser, Fernandes et al., 2009; Zachariah et al., 2006).

In recent years, programs such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and the United States government's President Emergency Plan for AIDS Relief (PEPFAR) have substantially expanded coverage and access to antiretroviral therapy (ART) free of charge in resource-limited settings around the world, including SSA. The expansion of ART coverage has transformed HIV/AIDS from an acute, life-threatening illness to a manageable, chronic condition. However, expansion and increased access to HIV treatment have produced unintended consequences such as exacerbating the relationship between food insecurity and HIV. Although many food-insecure PLHIV now have access to life-saving antiretroviral (ARV) drugs, their limited or lack of access to adequate and nutritious food at all times constrains them from meeting the food and nutritional requirements of ART. Food insecurity among PLHIV may contribute to delayed or non-initiation of treatment. For those who are receiving treatment, food insecurity may reduce PLHIV's ability to maintain optimal ART adherence.

An emerging body of evidence has shown that food insecurity acts as a barrier to optimal ART adherence in resource-adequate and resource-limited settings (Kalichman et al., 2011, 2014; Young, Wheeler, McCoy, & Weiser, 2014; Weiser et al., 2010). Food insecurity can contribute to suboptimal ART adherence in several ways: 1) ART can increase appetite and may lead to intolerable hunger in the absence of food; 2) side effects of ARV drugs can be severe in the absence of food; 3) PLHIV may skip doses because they cannot afford the added nutritional burden to optimize treatment outcomes; and 4) competing demands between costs of food and health expenses may lead to default from treatment (Weiser et al., 2010; Young et al., 2014).

ART has been shown to be effective in reducing mortality and increasing survival among PLHIV who remain in treatment and adhere to therapy optimally (Bangsberg et al., 2001; Wood et al., 2006). Nonadherence or missing 5 to 10% of doses is strongly associated with mortality (Stringer et al., 2006), decline in CD4 cell counts (Paterson et al., 2000), and development of drug-resistant HIV (Hecht et al., 1998).¹ Nonadherence can negate the clinical benefits of the only medications currently available in SSA. Never before has a treatment regimen required strict lifetime adherence with devastating consequences for nonadherence.

Food insecurity is highly prevalent in SSA (FAO, World Food Programme [WFP], & International Fund for Agricultural Development [IFAD], 2012; Rosen, Meade, Fuglie, & Rada, 2014). In many places, the prevalence of food insecurity among PLHIV is well above general population estimates (Hong et al., 2014; Musumari et al., 2014; Tsai et al., 2011). ART programs in SSA have reported high percentages of food-insecure patients. For instance, more than 60% of PLHIV enrolled in ART programs in Ethiopia (Tiyou, Belachew, Alemseged, & Biadgilign, 2012), Kenya (Nagata et al., 2012; Mamlin et al., 2009), Namibia (Hong et al., 2014), Uganda (Tsai et al., 2011; Weiser et al., 2014), and Zambia (Samuels & Rutenberg, 2011) are food-

¹ CD4 cell is a type of white blood cell that is critical to the proper and efficient functioning of the immune system to fight infection. HIV weakens the immune system by destroying CD4 cells. CD4 cell count is a laboratory test that measures the number of CD4 cells in a sample of blood. The CD4 count is the most important indicator of immune function and strongest predictor of HIV progression (National Institutes of Health [NIH], n.d.).

insecure. High rates of food insecurity among ART patients may limit the effectiveness of ART expansion to improve HIV-related outcomes and quality of life among PLHIV. Research has shown that food insecurity is emerging as a critical barrier to ART treatment initiation and optimal ART adherence among PLHIV in SSA (Singer, Weiser, & McCoy, 2015; Weiser et al., 2010, 2014).

Even though PLHIV are provided information on drug-food interactions and the importance of good nutrition, merely providing information is often inadequate particularly if PLHIV are poor and lack financial resources to afford the food they need. Poor PLHIV become less likely than their non-poor counterparts to maintain proper nutrition to strengthen the immune system, manage opportunistic infections, and optimize treatment outcomes. Understanding specific constraints poor PLHIV face in accessing food, particularly the underlying determinants of food insecurity in HIV/AIDS-affected households, is important to maintain optimal treatment adherence and enhance the capability of PLHIV to live productive and meaningful lives.

Given importance of optimal treatment adherence to survival and health, efforts to improve ART adherence for PLHIV in SSA have been tested and implemented. Evidence indicates effectiveness of several types of interventions in improving antiretroviral adherence (Bärnighausen et al., 2011; Mills et al., 2014). Although many interventions (e.g., directly observed therapy, peer supporters, and mobile-phone text messages) focus on patient-level barriers and target patients regardless of food security status, a number of programs have directly tackled lack of food as a barrier to ART adherence. Most of these programs provide short-term food ration to PLHIV and, in some instances, their households (Audain, Zotor, Amuna, & Ellahi, 2015; Tirivayi & Groot, 2011). These food assistance programs do not offer sustainable and stable access to food, and rarely address underlying determinants of food insecurity. Increasingly, livelihood programs are being integrated with HIV treatment as a way to increase ART adherence and improve food security (Aberman, Rawat, Drimie, Claros, &

Kadiyala, 2014; Pandit et al., 2010). Integrated HIV and livelihood programs (IHLPs) may be a promising approach to address the intersecting issues of food insecurity and HIV in resource-limited settings. However, few IHLPs have been systematically and rigorously evaluated. Compared with other adherence interventions (including food assistance programs), limited evidence exists on the effectiveness of IHLPs in increasing food security and improving ART adherence. These gaps in research impede adoption of IHLPs as a policy option and as part of strategic programming to address HIV treatment barriers in SSA.

The objectives of this dissertation are two-fold: 1) to expand the literature on food insecurity and ART adherence in resource-limited settings, particularly in rural communities; and 2) to address critical research gaps on the effectiveness of an integrated HIV and livelihood program on health and wellbeing of ART patients. This dissertation aims to investigate and describe an evidence-informed narrative about the intersecting relationship of food insecurity and ART adherence in Lundazi District, Eastern Province, Zambia, and a promising approach to improve food security and HIV treatment adherence. The organization of the dissertation is as follows. Chapter 1 reviews and synthesizes the current literature on food insecurity and HIV/AIDS in SSA. Chapter 1 describes the reciprocal link between food insecurity and HIV/AIDS, role of food insecurity on ART adherence, and current state of interventions to improve food security and ART adherence in SSA and other resource-limited settings. Chapter 1 concludes with background information about Zambia.

Chapter 2 defines the theories that help explain the intersecting relationship of food insecurity and ART adherence. Building on these theoretical models, Chapter 2 also outlines an integrated conceptual framework that informs a program model for a food security intervention. Chapter 2 ends with definition of key concepts delineated in the program model and the dissertation's research questions. The four research questions are:

- 1) What is the prevalence of food insecurity in a sample of rural ART patients in Eastern Province, Zambia?

- 2) What are the risk factors associated with food insecurity among PLHIV in rural Eastern Province, Zambia?
- 3) What is the relationship between food insecurity and ART adherence among PLHIV in rural Eastern Province, Zambia?
- 4) What is the impact of participation in an IHLP on food security and ART adherence?

Chapter 3 explains the research design and methods, including description and implementation of a livelihood intervention. Chapter 3 also describes the project setting and recruitment process, defines data collection procedures and key study measures, and outlines the analysis plan for each research question. Chapter 4 presents results, including descriptive, bivariate, and multivariate findings for each research question. Findings include the prevalence and correlates of food insecurity, the relationship between food insecurity and ART adherence, and the impacts of an IHLP on food security and ART adherence. Chapter 5 discusses study findings and implications for social work policy, practice, and research. Chapter 5 also explains key study limitations and ends with concluding remarks.

CHAPTER 1: BACKGROUND AND SIGNIFICANCE

Food Insecurity and HIV/AIDS in sub-Saharan Africa

Sub-Saharan Africa remains the world's most vulnerable region to food insecurity. In 2014, an estimated 258 million people in the region were food insecure. By 2024, the number of food insecure people in SSA is projected to increase to 346 million (Rosen et al., 2014). Furthermore, of the 35 million people living with HIV globally, 25 million are living in SSA (UNAIDS, 2014). SSA remains the region most severely affected by HIV, accounting for 71% of the people living with HIV worldwide. Nearly one in every 20 adults (15–49 years) in the region is living with HIV. However, progress is being achieved as new HIV infections and AIDS-related deaths are declining and antiretroviral therapy (ART) coverage is expanding in the region. Between 2005 and 2013, the number of new HIV infections decreased by 33%. Rapid expansion of ART coverage and access continues to save lives. Since 1995, ART has added 9 million life-years in SSA (UNAIDS, 2012). In 2013, 39% of adults living with HIV were receiving ART. The steady decline in HIV incidence and rapid increase in access to ART have contributed to the decline in the number of people dying from AIDS-related causes. Between 2005 and 2013, the number of AIDS-related deaths in the region decreased by 39% (UNAIDS, 2014).

The overall trend in SSA reflects the patterns, successes and challenges related to food insecurity and HIV/AIDS in Zambia – the focal country of this dissertation. For instance, an estimated six million Zambians (or 43% of the population) were food insecure and undernourished during 2011 to 2013 (FAO, IFAD, & WFP, 2013). HIV/AIDS remains a national priority. The country's HIV prevalence rate in 2013 was estimated at 12.5%. This prevalence level translates to 1.1 million people (of all ages) who are living with HIV, including 960,000 adults. The country accounts for 4% of all people living with HIV (PLHIV) in SSA. However,

progress is also being achieved in Zambia as new HIV infections and AIDS-related deaths are declining and ART coverage is expanding, consistent with overall trend in SSA. The number of new infections in the country decreased from an estimated 92,000 in 2005 to 54,000 in 2013 (UNAIDS, 2014). In addition, 55% of eligible adults were receiving ART; one of the highest coverage in SSA. Consequently, rapid expansion of ART continues to save lives and reduce AIDS-related mortality. The number of AIDS-related deaths markedly declined from 68,000 in 2005 to 27,000 in 2013 (UNAIDS, 2014). Despite progress in reducing new HIV infections and increasing survival of PLHIV, food insecurity is increasing and a considerable proportion of the population remains affected by HIV/AIDS. This substantial fraction of the population experiencing food insecurity and living with HIV/AIDS may indicate substantial co-occurrence of food insecurity and HIV/AIDS in SSA, including Zambia.

Interaction of Food Insecurity and HIV/AIDS in SSA: A Reciprocal Link

The convergence of food insecurity and HIV creates a cycle, with food insecurity contributing to choices and behaviors that increase risk to HIV exposure and infection, and HIV in turn worsens susceptibility to food insecurity by limiting income and food production (Gillespie & Kadiyala, 2005; Weiser et al., 2011). Consistent with evidence in the general population, food insecurity also negatively influences various health outcomes and quality of life of PLHIV. The next two subsections critically examine the interaction of food insecurity and HIV. First, I explain one half of the reciprocal link – how HIV/AIDS contributes to food insecurity. Second, I illustrate the other half of the reciprocal link – how food insecurity increases risk of HIV acquisition. The last two sections of Chapter 1 define food insecurity and describe the evidence on the importance of food and nutrition for PLHIV and the effects of food insecurity on health outcomes of PLHIV.

HIV/AIDS contributes to food insecurity. Although numerous factors (e.g., poverty and unemployment) contribute to food insecurity, HIV/AIDS has exacerbated food insecurity in SSA (Beegle, de Weerd, & Dercon, 2008; Chapoto & Jayne, 2008; de Waal &

Whiteside, 2003; Garcia et al., 2013; Weiser et al., 2010). HIV/AIDS contributes to food insecurity in at least three ways. First, HIV/AIDS might lead to loss or reduction in income. When working-age adults become ill, households lose income from reduced labor productivity either through inability to be present at work and/or conduct income-generating activities outside formal employment. Limited income, in turn, constrains households' ability to access food. Evidence suggests that HIV-positive workers in SSA earn less income than HIV-negative workers primarily because of decreased work attendance and productivity (Donovan & Massingue, 2007; Fox et al., 2004; Larson et al., 2013). Further, less income has driven households to reduce food intake (Thangata, Hildebrand, & Kwesiga, 2007), including consumption of less nutritious food (Donovan & Massingue, 2007; Gill, 2010). Less income also deprives households of opportunities to save and accumulate assets, which in turn, buffers against consumption shocks (Hulme & Shepherd, 2003; Moser, 2007). For households that produce their own food, HIV/AIDS might also affect food production when sick adult members cannot go to the field. For land-owning households, HIV/AIDS leads to loss of land possession, which in turn, diminishes households' ability to produce food and generate income (Parker, Jacobsen, & Komwa, 2009). In other words, HIV/AIDS can lead to loss of assets or livelihood sources in addition to income loss. HIV/AIDS also increases care-giving responsibilities of other household members (Kipp, Tindyebwa, Rubaale, Karamagi, & Bajenja, 2007; Sefasi, 2010), which takes time away from work and affects ability to earn income and/or obtain food.

Second, HIV/AIDS might increase household expenditures related to HIV treatment. Competing demands might force households to reduce food intake or forego food consumption in order to afford treatment costs or pay for funeral expenses. AIDS-affected households incur more and higher health-care expenses (Gregson, Mushati, & Nyamukapa, 2007; Kaler, Alibhai, Kipp, Rubaale, & Konde-Lule, 2010; Ngalula, Urassa, Mwaluko, Isingo, & Boerma, 2002), which further deplete household resources that can be used to purchase or produce food. In addition, when a household member dies from AIDS-related causes, funeral costs are an additional drain

on resources and become a major financial consequence of an AIDS-related death (Collins & Leibbrandt, 2007). In order to pay for funeral expenses, households may be compelled to reduce food consumption. Although ill-health generally requires more economic resources, HIV/AIDS leads to higher costs, particularly in resource-limited settings in SSA due to health service gaps such as low health care coverage, user charges/out-of-pocket payments, and poor quality of care (McIntyre, Thiede, Dahlgren, & Whitehead, 2006; Russell, 2004).

Third, PLHIV might not be able to rely on social support or informal safety net arrangements for food assistance because of stigma and discrimination against PLHIV, which remains prevalent in many part of SSA (Abrahams & Jewkes, 2012; Holzemer et al., 2009; Simbayi et al., 2007). In many resource-limited settings, informal safety nets through kin and social networks buffer against adverse effects of economic and health shocks, including limited access to food (de Weerd & Dercon, 2006; la Ferrara, 2003). For instance, individuals and households belonging to the same social support network might share meals, borrow money from each other, or obtain direct food assistance. However, stigma and discrimination hinder PLHIV and their households from drawing on informal support for food assistance (Dawson, 2013; Kaschula, 2011; Tsai et al., 2011). For instance, when a person's HIV positive status is disclosed, family, friends, or community members might dissociate themselves, which might result in temporary or permanent dissolution of social support system. In turn, social exclusion and dissolution of social support system, due to stigma and discrimination, might exacerbate PLHIV's ability to earn income and obtain food.

Even in situations when PLHIV are not stigmatized or neglected, the ability of social support networks to provide assistance depends on whether such social networks have extra resources to spare. Contrasted with non-poor households, poor households' social network might not be able to adequately provide food assistance when the economic and financial welfare of the support system is also precarious and vulnerable to shocks. In many resource-limited settings, the mitigating effect of social support on food security tends to be less effective

among poor households than nonpoor households (Hadley, Mulder, & Fitzherbert, 2007). In other words, because of limited available resources, poor households might not be able to provide extra food when kin or neighbors require assistance. Further, high rates of AIDS-related deaths in many resource-poor communities have worsened the ability of social networks to extend assistance. In many places in SSA, the poor and their communities have been disproportionately affected by HIV/AIDS (de Waal & Whiteside, 2003; Whiteside, 2002). Many households within the same communities continue to face multiple episodes of HIV-related illnesses and AIDS-related deaths, which in turn, further constrain households' capacity to help other households in need. In other words, poverty and HIV/AIDS predictably and jointly diminish the ability of social support systems to ease food insecurity among HIV-affected households in resource-limited settings.

Food insecurity increases risk of HIV acquisition. Food insecurity increases risk of HIV infection through three pathways: nutritional, mental health, and behavioral (Gillespie & Kadiyala, 2005; Rollins, 2007; Weiser et al., 2011). First, food insecurity leads to skipped meals and intake of poor diet which results in macro and micronutrient deficiencies (Labadarios et al., 2011; Psaki et al., 2012). Nutrient deficiencies might increase risk of HIV acquisition through impairment of the gut and genital epithelial lining, which can increase susceptibility to HIV infection and efficiency of HIV transmission (Fawzi et al., 2002; Friis, 2006). Nutrient deficiency caused by food insecurity is also associated with higher risk of mother-to-child HIV transmission (Dreyfuss & Fawzi, 2002; Mehta et al., 2008; Semba et al., 1994). Further, food-insecure pregnant mothers living with HIV are less likely than food secure mothers to use maternal health services to prevent mother-to-child HIV transmission, which in turn, increases risk of HIV acquisition (McCoy, et al., 2015).

Second, food insecurity might contribute to increased risk of HIV acquisition through food insecurity's adverse effects on mental health and psychosocial wellbeing. In SSA, evidence suggests that food insecurity is associated with poor mental health status such as anxiety and

depression (Cole & Tembo, 2011; Hadley & Patil, 2008; Lund et al., 2010; Weaver & Hadley, 2009). Poor mental health, in turn, is strongly associated with high risk sexual behaviors (e.g., unprotected sexual intercourse and multiple concurrent sexual partners) that increase risk of HIV acquisition (Kinyanda et al., 2012; Sikkema et al., 2011). In addition to poor mental health status, food insecurity is associated with substance abuse, which in turn, influences engagement in risky sexual behaviors that heightens risk of HIV infection (Kalichman et al., 2012; Normén, et al., 2005; Pitpitan et al., 2012; Weiser et al., 2009). However, limited evidence from SSA (particularly outside South Africa) and other resource-limited regions exists to support the relationship between food insecurity and substance abuse, including illicit drugs or alcohol. In sum, the mental health pathway that links food insecurity with increased risk of HIV acquisition suggests a mediating role of poor mental health status and/or substance abuse.

The third pathway that explains how food insecurity increases risk of HIV transmission is through engagement in high-risk sexual behaviors and/or occupations that are prone to sexual risk taking as a way to cope with food insecurity; with women at a higher risk of engaging in unsafe sexual practices and precarious occupations (Greif, 2012; McLachlan, et al., 2009; Mill & Anarfi, 2002; Miller et al., 2011; Scorgie et al., 2012). Inadequate access to food has been shown to be associated with inconsistent condom use with a nonprimary partner, sex exchange, intergenerational sexual relationships, and lack of control in sexual relationships among women (Dunkle et al., 2004; Oyefara, 2007; Weiser et al., 2007), which in turn, increases risk of HIV acquisition. In many communities in SSA, food insecurity has also forced household members (mostly women) to become sex workers to earn income and cope with food insecurity and hunger in their households (Fielding-Miller, Mnisi, Adams, Baral, & Kennedy, 2014; Scorgie et al., 2012). Higher levels of food insecurity have driven sex workers to engage in unsafe sexual practices (most notably, sex without a condom) in exchange for getting paid more money (Agha & Chulu Nchima, 2004; Matovu & Ssebadduka, 2013; Ntumbanzondo, et al., 2006). Sex without condoms particularly with multiple casual and concurrent partners heightens risk of HIV

infection (Boerma & Weir, 2005). In addition to sex work, food insecurity might influence one's decision to migrate for work. In many communities in SSA, migration for work is associated with increased sexual risk taking and HIV infection (Camlin, Kwen, Dworkin, Cohen, & Bukusi, 2014; Lagarde et al., 2003; Lurie et al., 2003; Weine & Kashuba, 2012). For many migrants, sex work often becomes a livelihood activity (Richter, Luchters, Ndlovu, Temmerman, & Chersich, 2012). Consistent with the overall pattern of sexual risk taking, migrant sex workers often engage in risky sexual behaviors (such as sex without condoms, multiple concurrent sexual partnerships) in order to earn more money and cope with food insecurity (Richter et al., 2014).

Definition of Food Insecurity

Food insecurity is a multidimensional construct commonly conceptualized in three dimensions: availability, access, and utilization (FAO, 1996; Maxwell & Frankenberger, 1992; Webb et al., 2006; Woller et al., 2011). Availability refers to physical existence or supply of food. Access refers to resources that individuals and households have to obtain food either through own production or in the marketplace. Utilization refers to actual food that is consumed by individuals and households, including the quality of food storage and preparation, diversity of diet, and intra-household food allocation. In general, the three dimensions (availability, access and utilization) are hierarchical and linear in nature. However, although food availability is necessary, availability is not sufficient to ensure adequate access to food. Similarly, access is necessary but not sufficient for utilization, including intake of nutritious and safely prepared and stored food. In addition, food security is characterized by stability of all three dimensions over time. For instance, even if a household has adequate access to food today, that same household is still considered food insecure if access is insufficient on a periodic basis. In other words, adequate access to food must be at all times.

Access, or the ability to obtain food, is closely associated with individual or household's social and economic standing (Barrett, 2010; Sen, 1981). Access reflects the demand side of food security, including acquisition and allocation of food within and between households. The ability

to access food is determined by an individual or household's economic and social resources. Economic resources include cash income (from labor-related activities or social assistance programs) and assets (e.g., savings) that can be used to buy food or purchase materials to produce food. Social resources cover safety net arrangements between individuals, households, and communities. In many resource-limited settings, food sharing extends beyond the immediate household. Generally, food is shared at one point in time in exchange for food (or other resources) at some later time (Kaplan & Gurven, 2005; Ndirangu et al., 2014). Unlike availability and utilization, access to food is directly affected by economic and health shocks such as loss or reduction in labor productivity due to chronic conditions such as HIV/AIDS (Barrett, 2010). Because access is closely related to individual and household socioeconomic status, food insecurity is primarily defined in this dissertation as inadequate or lack of access to food at all times.

In the literature, food insecurity is also defined based on duration and level of severity (Maxwell & Frankenberger, 1992). Food insecurity can be chronic or transitory. Chronic food insecurity is long-term and persistent, and occurs when individuals and households are unable to access food over an extended period of time. On the other hand, transitory food insecurity is short-term and temporary. Transitory food insecurity occurs when individuals and households experience a sudden but momentary drop in their ability to access food (Maxwell & Smith, 1992). Although duration differs, chronic and transitory food insecurity results from reduction in financial and social resources partly due to economic (e.g., poverty, unemployment, or lack of assets) and health (e.g., living with HIV or other chronic conditions) shocks. Food insecurity can also be seasonal. Seasonal food insecurity occurs when individuals or households experience recurrent inability to access food. Seasonal food insecurity can happen because of periodic employment interruptions or cyclical food production patterns. For instance, in many rural areas in SSA, households obtain income and food from farming, which in turn, is seasonal due to periodic variations in climate and crop patterns. Seasonal food insecurity can be viewed as

transitory or chronic. Seasonal food insecurity is transitory because inadequate access is temporary and short-lived, but it is also chronic because the inability to access food is predictable and recurring (Maxwell & Smith, 1992).

Access to food can also be classified based on level of severity – food secure, mildly food insecure, moderately food insecure, and severely food insecure. These categories of food insecurity refer to the frequency and severity of coping strategies that individuals and households use when experiencing inadequate access to food (Coates, Swindale, & Bilinsky, 2007; D. Maxwell, 1996). A food secure household experiences none of the food insecurity-related condition, or rarely worries that the household would not have adequate food. A mildly food insecure household worries more frequently (at least three times or more in the past four weeks) that the household would not have adequate food contrasted with a food secure household. In addition to food access anxiety, a mildly food insecure household is unable to eat preferred foods and/or eats a more monotonous or less diverse diet than desired, but only rarely (or once or twice in the past four weeks). However, a mildly food insecure household does not cut back on quantity of food nor experience any of the three most severe conditions (running out of food, going to bed hungry, or spending a whole day or night without eating).

A moderately food insecure household, on the other hand, forgoes the quality of food they eat more frequently. For example, a moderately food insecure household eat a monotonous or less desired foods more frequently (at least three times or more in the past four weeks). A moderately food insecure household has also started to cut back on quantity of food by reducing the size of meals or number of meals, but does not experience any of the three most severe food security-related conditions. For a moderately food insecure household, the reduction in the quantity of food happens rarely or sometimes (i.e., between once to ten times in the past four weeks).

A severely food insecure household reduces the quantity of food either by cutting back on the size of meals or number of meals, and either of these conditions occurs more than ten times

in the past four weeks. In addition, a severely food insecure household experiences any of the three most severe conditions – running out of food, going to bed hungry, and spending whole day and night without eating – regardless of frequency of occurrence. For instance, a household that ran out of food even once in the past four weeks is considered severely food insecure (Coates et al., 2007).

Combining the “access” dimension of food insecurity with duration and level of severity provides a clear yet complex picture of food insecurity. An individual might experience a mild but chronic form of food insecurity. Similarly, a household might suffer from a severe and chronic form of insecurity. Defining food insecurity is a continuous process that has already seen significant changes, including the shift to individual and household experiences of food insecurity, and use of both objective indicators and subjective perception of food insecurity (S. Maxwell, 1996). Ultimately, accuracy in defining food insecurity contributes to well-informed research, policy and practice.

Importance of Food and Nutrition for PLHIV

Food and nutrition are important for PLHIV regardless of ART treatment status. For ART-naïve PLHIV (or those not yet in need of treatment), adequate food and proper nutrition are critical to improve overall health and nutritional status, prevent malnutrition, extend period of asymptomatic infection, boost immune system to fight opportunistic infections, support recovery from infections, and slow disease progression (de Pee & Semba, 2010; Salomon, De, & Melchior, 2002; Katona & Katona-Apte, 2008; Ivers et al., 2009). For ART-experienced PLHIV (or those receiving treatment), adequate food and proper nutrition are critical to improve the effectiveness of ARVs, optimize treatment outcomes, regain energy and strength, maintain body weight, and minimize side effects of medications (Drain, Kupka, Mugusi, & Fawzi, 2007; Food and Nutrition Technical Assistance Project [FANTA], 2004; McDermott et al., 2003; Semba & Tang, 1999). Regardless of treatment status, food is also important because PLHIV require additional energy to compensate for the energy used to manage HIV and opportunistic

infections, nutrient malabsorption and altered metabolism (FANTA, 2004; Salomon et al., 2002; Shevitz et al., 1999). For asymptomatic cases, PLHIV are recommended to increase energy intake by 10% over the level of energy intake recommended for a healthy non-HIV-infected person of the same age, sex, and physical activity level (FANTA, 2004; Kosmiski, 2011). For symptomatic cases, PLHIV are recommended to increase energy intake by 20% to 30% over the level of energy intake recommended for a healthy non-HIV-infected person of the same age, sex, and physical activity (FANTA, 2004; World Health Organization [WHO], 2003). Adequate access to food and nutritious diet provide needed energy during all stages of HIV infection. For many food-insecure PLHIV, meeting the added energy requirements that are 10% to 30% higher than the requirements for healthy individuals can be very challenging.

Food insecurity predicts adverse health outcomes of PLHIV. Consistent with research in the general population (Dewing, Tomlinson, le Roux, Chopra, & Tsai, 2013; El-Sayed et al., 2010; Hadley & Patil, 2006) and in people living with chronic diseases other than HIV (Seligman, Bindman, Vittinghoff, Kanaya, & Kushel, 2007; Semba, Darnton-Hill, & de Pee, 2010), evidence suggests that, regardless of treatment status, food insecurity is associated with adverse health outcomes among PLHIV (Katona & Katona-Apte, 2008; Piwoz, 2004). In SSA, food insecurity has been shown to increase risk of being underweight and wasted (Kadiyala & Rawat, 2013), opportunistic infections and frequent hospitalizations (Weiser et al., 2012), and mortality (de Pee & Semba, 2010, Koethe et al., 2013, Rawat, McCoy, & Kadiyala, 2013) among PLHIV. In both resource-limited and resource-adequate countries, food insecurity is also associated with lower physical health-related quality of life (Choi et al., 2015; Weiser et al., 2012) and poor mental health status such as depression (Choi et al., 2015; Heylen, Panicker, Chandy, Steward, & Ekstrand, 2015; Tsai et al., 2012; Wu et al., 2008) among PLHIV, consistent with evidence in the general population (Okechukwu et al., 2012). Poor psychosocial health of PLHIV might result in worsened HIV-related outcomes, including nonadherence to treatment (Carrico et al., 2011; Mills et al., 2006). Among PLHIV receiving ART, food insecurity has been

shown to be associated with adverse treatment-related outcomes, including lower CD4 cell counts (Kalichman et al., 2010; McMahon, Wanke, Elliott, Skinner, & Tang, 2011; Mendoza, Matshaba, Makhandia, & Anabwani, 2014; Weiser, Bangsberg et al., 2009) and incomplete HIV viral suppression (Feldman, Alexy, Thomas, Gambone, & Irvine, 2015; Kalichman et al., 2015; Wang et al., 2011; Weiser, Frongillo et al., 2009). Evidence also indicates that food insecurity has direct effect on treatment outcomes, and the relationship is not mediated by treatment adherence level nor body mass index (Wang et al., 2011). The potential effect of food on pharmacokinetics of ARV drugs might explain the direct association between food insecurity and poor treatment outcomes such as incomplete viral suppression (Boffito et al., 2005; Sekar et al., 2007). In other words, the interaction of not having food while taking ARV drugs might reduce treatment efficacy, which in turn, contributes to poor treatment outcomes.

Summary

An extensive body of literature supports the bidirectional link between food insecurity and HIV. One half of the relationship shows that being food insecure increases the risk of HIV infection through three pathways: nutritional, mental health, and behavioral. The other half of the relationship suggests that being HIV positive heightens the risk of food insecurity through various pathways including loss of income, higher health care expenses, and diminished social support due to stigma and discrimination. These pathways are not mutually exclusive; and thus, it is possible for a food-insecure individual to be nutrient deficient, experience chronic mental distress, and engage in high-risk sexual behaviors. All these pathways exacerbate one's risk of HIV acquisition. Similarly, an HIV-positive individual might have lost sources of income but still need to pay for ancillary treatment costs, while at the same time losing social support that can help provide food and other basic needs. These cumulative risks heighten one's vulnerability to food insecurity. Consequently, food-insecure PLHIV have also engaged in high-risk behaviors (such as sex work) to earn income in order to keep food on the table and pay for other basic needs (e.g., Fielding-Miller et al., 2014; MacLachlan et al., 2009). In turn, PLHIV's engagement

in high-risk occupations creates mechanisms that facilitate HIV transmission to HIV-negative partners. Further, food insecurity contributes to a broad range of adverse health outcomes for PLHIV, including mortality, morbidity, and poor mental health. Unless appropriate interventions are put in place, the cycle will persist and continue to negatively affect efforts to reduce new HIV infections and promote higher quality of life (physical and mental) for PLHIV. The importance of food on HIV risk reduction and survival of those who are living with HIV underscores the broad social and public health implications for promoting adequate access to food, particularly in resource-limited communities in SSA.

Food Insecurity and Antiretroviral Therapy Adherence in sub-Saharan Africa

The expansion of ART coverage in SSA has provided life-saving drugs to millions of PLHIV. However, scaling up access presents new challenges for millions of low-income PLHIV who now have access to ART but remain without adequate access to food necessary to optimize treatment outcomes and ease drug side-effects. ART expansion and access to HIV treatment have inadvertently added another dimension to the relationship between food insecurity and HIV, i.e., food insecurity contributes to rapid disease progression from HIV to AIDS primarily through suboptimal adherence to treatment. Although numerous factors predict optimal adherence to ART (Kagee et al., 2011; Langebeek et al., 2014; Mills et al., 2006) in SSA, food insecurity is increasingly becoming a critical barrier to optimal ART adherence (Hardon et al., 2007; Hong et al., 2014; Singer et al., 2015; Weiser et al., 2010; Young et al., 2014). The negative effect of food insecurity on ART adherence is one mechanism through which food insecurity contributes to HIV progression and adverse health outcomes among PLHIV. Food insecurity and nonadherence to treatment might impede efforts to control HIV and reduce deaths from AIDS-related illnesses, as well as improve the quality of life for PLHIV. Without optimal adherence to ART, the substantial progress that has been achieved to improve access to treatment would not equal to longer, healthier lives for PLHIV in SSA and elsewhere in the world.

Definition of Adherence

The World Health Organization defines adherence as the extent to which a person's behavior corresponds with agreed recommendations from a health care provider (Sabaté, 2003). This definition covers a broad range of health-related behaviors beyond taking prescribed drugs. These behaviors include seeking medical attention, attending follow-up appointments, filling prescriptions, and executing lifestyle changes such as following a healthier diet and doing regular exercises. The WHO definition also highlights the quality of patient and health care provider (be it a physician, nurse, or other health practitioner) relationships, as well as the active (versus passive) role of the patient in the treatment process (Sabaté, 2003). In the literature, adherence is preferred over the term "compliance" because the latter is considered judgmental and suggests blame for the patient (Julius, Novitsky, & Dubin, 2009).

Consistent with food insecurity, adherence can be viewed as a multidimensional construct. However, most adherence studies including those on ART have focused on medication adherence. Within the narrower concept of medication adherence, adherence is viewed as a patient's agreement with the health care provider's recommendation with respect to timing (or schedule/interval), amount of medication (dose), and frequency of medication-taking during the prescribed length of time (Cramer et al., 2008). In other words, medication adherence refers to a patient's day-to-day medication-taking behaviors in accordance with the prescribed schedule, dose and frequency. Although medication adherence can refer to dose, schedule or frequency, most research on ART adherence has focused on dose adherence. Dose adherence is defined as the amount or proportion of medications taken by a patient relative to the amount or proportion of medications prescribed. Further, optimal dose adherence is generally defined as $\geq 95\%$ of prescribed ARV medications taken (Alexander et al., 2003; Pasternak et al., 2012; Paterson et al., 2000; Wood et al., 2006). However, some studies have shown that ART adherence level of $\geq 80\%$ or $\geq 90\%$ might be sufficient to achieve optimal

treatment outcomes (Bangsberg et al., 2001; Garcia de Ollala et al., 2002; Shuter, Sarlo, Kanmaz, Rode, & Zingman, 2007).

ART Adherence in SSA

ART has contributed to substantial decline in AIDS-related deaths and illnesses in SSA (Floyd et al., 2012; Jahn et al., 2008; Kasamba, Baisley, Mayanja, Maher, & Grosskurth, 2012; Walensky et al., 2008). In addition to higher survival and improved clinical outcomes, ART has led to improvements in economic, social, and psychological wellbeing of PLHIV in SSA (Beard, Feeley, & Rosen, 2009; Nachega et al., 2015; Patel et al., 2009; Wagner, Ghosh-Dastidar, Garnett, Kityo, & Mugenyi, 2012; Thirumurthy & Zivin, 2012), as well as the well-being of their children and families (d'Adda, Goldstein, Zivin, Nangami, & Thirumurthy, 2009; Zivin, Thirumurthy, & Goldstein, 2009). ART is also increasingly recognized as an effective tool to prevent HIV transmission (Anglemyer et al., 2013; Siegfried, van der Merwe, Brocklehurst, & Sint, 2011; White, Mirjahangir, Horvath, Anglemyer, & Read, 2014). However, access to ART alone does not equal to longer and better quality of lives for PLHIV. Adherence to ART is equally important to live longer and healthier. For PLHIV with access and able to adhere optimally on a daily basis, life expectancy now approaches that of people without HIV infection, particularly if therapy is started early (Mills et al., 2011; Nakagawa et al., 2012).

Although ART adherence levels in SSA have been shown to be higher than those in resource-adequate countries (Akileswaran, Lurie, Flanigan, & Mayer, 2005; Carlucci et al., 2008; Elul et al., 2013; Mills et al., 2006), one in four ART patients in SSA has poor adherence level (Mills et al., 2006). More recent studies have shown similar, if not worsening, patterns of lower or suboptimal ART adherence levels in the region, including Zambia (Jones, Cook, Spence, Weiss, & Chitalu, 2014; Safren et al., 2014; Vinikoor et al., 2014; Yaya et al., 2014). For instance, 14%, 40%, and 71% of ART patients in Tanzania, Uganda and Zambia have adherence levels of less than 80%, 90% and 100% in the past 30 days, respectively (Denison et al, 2015). Further, many studies that have examined adherence levels in SSA were based on patients with

early access to therapy, which tend to exhibit high adherence rates (Elul et al., 2013; Mills et al., 2006; Sasaki et al., 2012). Consistent with patterns in resource-adequate countries (Liu et al., 2006), studies in SSA have shown that ART adherence declines over time (Byakika-Tusiime et al., 2009; Meresse et al., 2013). In Cameroon, for instance, the proportion of always-adherent patients decreased from 84% at early phase (months 1-6) to 76% at maintenance phase (months 12 to 24; Meresse, et al., 2013). Similarly, in Zambia, the percentage of patients with near perfect adherence declined from 76% at month 1 to 66% and 70% at months 6 and 12, respectively (Jones et al., 2014). Therefore, health advocates are concerned that as time goes by and access to treatment in the region continues to expand and develop with time, ART patients might experience challenges to long-term ART adherence (Bangsberg & Mills, 2013) and poor or suboptimal adherence levels caused by a myriad of factors, one of which is food insecurity.

Data on patient HIV care and treatment retention raise concerns about longer-term and lifetime adherence to ART. Since the start of large-scale ART access in SSA, patient retention in ART programs has shown a consistent declining pattern – from 80% at the end of first year to 72% at the end of third year (Fox & Rosen, 2010). In a review of early ART programs in SSA, patient retention was even lower – about 60% of patients at the end of the second year (Rosen, Fox, & Gill, 2007). Consistent with previous estimates, a recent meta-analysis shows that the 36-month patient retention in SSA was at 65% (Fox & Rosen, 2015). Treatment retention rates are even lower among most-at-risk populations, including sex workers (Vuylsteke et al., 2015). Loss of contact, death, migration, and poor clinical outcomes remain the most common causes of attrition (Billong et al., 2012; Fox & Rosen, 2010; Koole et al., 2014; Mutasa-Apollo et al., 2014). In sum, poor patient retention and suboptimal ART adherence may offset positive benefits of ART expansion in the region. For instance, in Zambia, the expansion of ART services has not consistently reduced mortality due to poor patient retention and adherence (Rathod et al., 2014).

Factors affecting ART adherence in SSA. Consistent with other chronic diseases such as asthma, cancer, diabetes, and hypertension, factors affecting ART adherence can be classified into five dimensions: patient-related, therapy-related (or treatment regimen), condition-related (or disease characteristics), health care system (including patient-provider relationship and health facilities), and social and economic factors (Ammassari et al., 2002; Atkinson & Petrozzino, 2009; Ickovics & Meade, 2002; Peltzer & Pengpid, 2013; Posse, Meheus, van Asten, van der Ven, & Baltussen, 2008). In SSA, these dimensions have been shown to influence ART adherence (Kagee et al., 2011; Langebeek et al., 2014; Mills et al., 2006). *Patient variables* that affect ART adherence include sociodemographic (age, gender, education, and literacy) and psychosocial factors (anxiety, depression, substance use, stressful life events, knowledge and attitudes about HIV and its treatment). Consistent associations between patient-related factors (such as mental health status and patient demographics) and ART adherence have been observed in ART patients in SSA (Nakimuli-Mpungu et al., 2012; Oku, Owoaje, Ige, & Oyo-Ita, 2013; Mills et al., 2006; Reda & Biadgilign, 2012). *Therapy-related factors* include the number of pills prescribed, complexity of regimen (e.g., dosing frequency and food instructions), medication side-effects, type of ARV drugs, and duration of treatment. Evidence suggests that factors related to the treatment regimen predicts ART adherence in SSA (Denison et al., 2015; Reda & Biadgilign, 2012). *Condition-related factors* include stage and duration of HIV infection, symptoms (including lack of and severity), and concurrent opportunistic infections. Characteristics of HIV infection have been shown to affect treatment adherence among ART patients in SSA (Elul et al., 2013; Naidoo et al., 2013).

In addition to individual-level factors, characteristics of the *health care system* influence patients' medication adherence behaviors. Two aspects of the health care system that affect adherence are the quality of patient-provider relationship and health facilities. Patient-provider relationship covers the patient's overall satisfaction and trust in the provider, the patient's belief of the provider's competence, the affective tone of the relationship, and provider's

communication skills. Qualities of health facilities that might influence adherence include availability and accessibility of ART, ongoing access to health care facilities, waiting time and opening hours, and availability of social services for patients. In SSA, the quality of patient-provider relationship and health facilities predicts ART adherence (Grant, Logie, Masura, Gorman, & Murray, 2008; Nash, Wu, Elul, Hoos, & El Sadr, 2011; Reda & Biadgilign, 2012; Skovdal, Campbell, Nhongo, Nyamukapa, & Gregson, 2011). The fifth dimension that affects medication adherence is the *social and economic characteristics* of patients and their households. These social and economic factors include poverty-related barriers such as lack of income and assets, food insecurity, unstable living conditions, limited social support network, and stigma and discrimination. In SSA, studies have consistently shown that social and economic factors affect ART adherence (Dewing et al., 2015; Kagee et al., 2011; Lankowski, Siedner, Bangsberg, & Tsai, 2014; Rachlis, Mills, & Cole, 2011; Reda & Biadgilign, 2012).

Food Insecurity as a Barrier to ART Adherence

Although numerous factors affect adherence to ART (Langebeek et al., 2014; Mills et al., 2006; Posse, Meheus, van Asten, van der Ven, & Baltussen, 2008; Reda & Biadgilign, 2012), a growing body of quantitative and qualitative research has found food insecurity to be a consistent socioeconomic barrier to ART adherence among PLHIV in SSA (Singer et al., 2015; Weiser et al., 2010; Young et al., 2014). Studies conducted in the Democratic Republic of Congo, Botswana, Cameroon, Kenya, Malawi, Namibia, Rwanda, Tanzania, Uganda, and Zambia found that food-insecure PLHIV were less likely to optimally adhere to ART treatment compared with food-secure PLHIV (Au et al., 2006; Boyer et al., 2011; Cantrell et al., 2009; Hardon et al., 2007; Hong et al., 2014; McKinney, Modeste, Lee, Gleason, & Maynard-Tucker, 2014; Musumari et al., 2014; Murray et al., 2009; Unge et al., 2008; Weiser et al., 2010, 2014). In addition to its impact on adherence, food insecurity has been found to be a consistent predictor of treatment postponement and interruptions (Hardon et al., 2007; Mshana et al., 2006; Musheke, Bond, & Merten, 2013; Weiser et al., 2010). In other words, food insecurity acts as a barrier to different

phases of HIV treatment, from initiation to adherence. Although PLHIV are counseled about the importance of food and nutrition with ART, merely providing information is not enough when many PLHIV do not have access to food or lack financial resources to afford the food they need to optimize treatment effects and prevent adverse health outcomes. Consistent with evidence in SSA, food insecurity has also been shown to predict suboptimal ART adherence in other resource-limited countries (Franke et al., 2011) and resource-adequate countries (Kalichman et al., 2011, 2014; Weiser, Yuan et al., 2013).

Prevalence of food insecurity among people living with HIV. In resource-adequate and resource-limited settings, food insecurity is highly prevalent among PLHIV (Garcia et al., 2013; Kalichman et al., 2010; Normén et al., 2005; Anema, Vogenthaler, Frongillo, Kadiyala, & Weiser, 2009; Tsai et al., 2011). In some cases, prevalence of food insecurity among PLHIV is higher than prevalence in the general population (Anema et al., 2011; Weiser, Bangsberg et al., 2009). Several studies have demonstrated that food insecurity is common among PLHIV in SSA, regardless of their treatment status. In Namibia, 92% of PLHIV reported experiencing food insecurity, with 67% living in households with severe food insecurity (Hong et al., 2014). Similarly, in the Democratic Republic of Congo, 57% of PLHIV were food insecure, with 51% reported being severely food insecure (Musumari et al., 2014). In Uganda, >70% of ART patients were food insecure, with >35% reported being severely food insecure (Tsai et al., 2011; Weiser et al., 2014). High rates of food insecurity (i.e., >50% of the sample) were also found among PLHIV participating in ART programs in Ethiopia (Tiyou et al., 2012), Kenya (Mamlin et al., 2009; Nagata et al., 2012), and Zambia (Samuels & Rutenberg, 2011).

Food insecurity not only affects PLHIV but also their households. The adverse effects of HIV on labor productivity of working adults (or heads of household) might explain the high prevalence of food insecurity among HIV-affected households. Because working adults living with HIV are more likely to miss work days and earn less income, their households have fewer financial resources to obtain food. In addition to reduced income, higher health expenses that

are incurred by HIV-affected households further constrain resources that could otherwise be used to obtain food and maintain consumption patterns. In Kenya, for instance, almost all households (99%) with at least one HIV-positive member experienced food insecurity, with 74% of households considered severely food insecure (Mbugua et al., 2008). For many PLHIV and their households, food insecurity affects the timing, frequency and dietary diversity of the food they eat. One coping strategy is to eat fewer meals per day and fewer types of food per meal (Bukusuba, Kikafunda, & Whitehead, 2007; Tiyou et al., 2012).

Correlates of food insecurity among people living with HIV. At least two unique factors contribute to higher risk of food insecurity among PLHIV. First is the impact of HIV/AIDS on income, health care expenses, and care-giving responsibilities. Unlike food insecurity in populations without chronic health conditions, PLHIV suffer from impaired health functioning that limits their ability to work and earn income. Most PLHIV are between the ages of 15 to 45 years (UNAIDS, 2014), the most economically productive age group and often the primary breadwinners or heads of household. An HIV-positive worker is more likely to miss work due to sickness and earn less income, which result in fewer financial resources to purchase or produce food (Donovan & Massinque, 2007; Fox et al., 2004). Further, HIV increases expenditures on health and medical care (Ngalula et al., 2002; Gregson et al., 2007). Higher health costs further deplete limited resources, which in turn, might compel HIV-affected households to forego food in order to afford medical care. HIV also increases care-giving burdens of other household members (Kipp et al., 2007; Sefasi, 2010), which takes time away from work and affects ability to earn income. Consequently, lack of income is a major risk factor for food insecurity among PLHIV in SSA (Bukusuba et al., 2007; Kaschula, 2011; Tiyou et al., 2012). However, few studies in SSA have investigated the effects of high health costs and increased care-giving responsibilities on food security of PLHIV and their households. Nonetheless, evidence from other resource-limited countries suggests high medical costs

associated with being HIV positive increase the risk of economic impoverishment, including food insecurity (Sharma, Krishnaswamy, & Mulay, 2015).

Second, stigma and discrimination might restrain the ability of food-insecure PLHIV and their households to rely on their social support networks for food assistance. Among PLHIV, social support (kin and informal networks) provides a way to cope with food insecurity by drawing on family and/or community members for food aid (Kaschula, 2011; Tsai et al., 2011, 2012). Unlike other chronic health conditions, HIV remains highly stigmatized (Abrahams & Jewkes, 2012; Kidia et al., 2015; Simbayi et al., 2007), which might lead to weakening or dissolution of existing support system. In Uganda, for instance, HIV-related stigma reduces ability of PLHIV to depend on social networks for food assistance, which in turn, heightens their risk of food insecurity (Tsai et al., 2011). In Swaziland, PLHIV recognize that their HIV status worsens their ability to access food through their own social networks (Fielding-Miller et al., 2014). In addition, PLHIV might suffer from poor mental health (e.g., depression) and harbor internalized stigma that might lead to social isolation and prevent them from accessing help to secure food.

In addition to lack of income and stigma, other factors that predict food insecurity include gender (women are more susceptible to food insecurity), age (older PLHIV are more susceptible to food insecurity), marital status (married PLHIV are less susceptible to food insecurity), larger household size, low educational attainment, low household asset-ownership, unstable living conditions (e.g., poor housing quality), unemployment, and limited social support (Bukusuba et al., 2007; McCoy, Ralph, Njau, Msolla, & Padian, 2014; Nagata et al., 2012; Tiyou et al., 2012; Tsai et al., 2011). Asset ownership, in particular, plays an important role in protecting families against food insecurity. In many communities in SSA, assets are utilized to generate income, which in turn, allows households to obtain or produce food (Barrett, Reardon, & Webb, 2001; Carter & May, 1999; Chowa, Masa, & Sherraden, 2012). In many instances, these income-generating assets form household livelihood strategies. Evidence also suggests that HIV-

afflicted households often sell their assets to cope with food insecurity (Bukusuba et al., 2007; Laar et al., 2015; Samuels & Rutenberg, 2011). Alternatively, low asset households tend to experience severe and more frequent food insecurity compared with high asset households (Tsai et al., 2011). Some types of assets also have direct effect on food security. Livestock and agricultural crops, for example, provide immediate sources of food. In addition to selling livestock or agricultural produce for cash returns, ART patients and their households might rely on some of these assets to feed and nourish them. In other words, asset ownership buffers the adverse effect of household food insecurity by providing tangible resources to draw on to smooth consumption patterns in times of income and health shocks. However, for asset-poor households, coping strategies may not include utilizing cash returns generated from assets.

In sum, consistent with predictors of food insecurity in the general population in SSA (Garrett & Ruel, 1999; Leyna et al., 2007; Misselhorn, 2005; Singh, Bhoopathy, Worth, Seale, & Richmond, 2016), indicators of poverty and low socioeconomic status contribute to higher risk of food insecurity among PLHIV and their households. Similarly, predictors of food insecurity among PLHIV in SSA are consistent with correlates of food insecurity among PLHIV in resource-adequate settings (Anema et al., 2011; Normén et al., 2005; Vogenthaler et al., 2010; Weiser, Bangsberg et al., 2009).

How Food Insecurity Contributes to Treatment Nonadherence

Food insecurity can contribute to suboptimal ART adherence, as well as treatment delay, interruption and early termination in several ways. The four most common mechanisms through which food insecurity adversely affects adherence behaviors include: 1) the belief that when on ART adequate food should be eaten to optimize treatment outcomes; 2) intolerable hunger due to increased appetite from being on ART; 3) severe side effects of ARV drugs when taken without food; and 4) competing demands to either put food on the table or pay for ancillary treatment costs (Young et al., 2014; Singer et al., 2015; Weiser, Tuller et al., 2010). Also, two additional pathways (medication diversion and effects of food insecurity on mental

health) may explain the association between food insecurity and suboptimal treatment adherence.

Perceived food requirements of ART. PLHIV may believe that they should not begin ART at all or skip doses if they are not able to maintain a balanced diet and meet the added nutritional requirements, or if they simply do not have food to maximize efficacy of ARV drugs and effectiveness of ART. Word-of-mouth from family, friends and other ART patients, as well as advice from health workers about the importance of taking ARVs with a balanced and nutritious diet may influence PLHIV's belief that food and nutrition is paramount to optimize treatment effects. The perceived food requirements, in turn, make food-insecure PLHIV hesitant to begin treatment or unable to optimally adhere to treatment. Evidence suggests that perceived food and nutritional demands are an obstacle to treatment among ART patients in SSA (Hardon et al., 2007; Weiser et al., 2010). ART patients regularly skip doses or not take their pills as prescribed when they do not have enough food to eat (Fielding-Miller et al., 2014; Musumari et al., 2013; Olupot-Olupot et al., 2008; Sanjobo, Frich, & Fretheim, 2008; Senkomago, Guwatudde, Breda, & Khoshnood, 2011; Skovdal et al., 2011). Lack of food and a perceived risk of having severe side effects associated with taking ARV drugs on an empty stomach also discourage PLHIV in initiating treatment (Mshana et al., 2006; Unger et al., 2008). In some cases, and in spite of health workers' suggestion to take medications even without food, ART patients remain reluctant to take their medication on an empty stomach (Hardon et al., 2007). This reluctance suggests that patients may fear other effects of the medication, beyond treatment efficacy, when taken without food. In sum, the belief that treatment is not as effective when taken without food illustrates one mechanism of how food insecurity affects adherence.

Increased appetite and hunger. ARVs can increase appetite and lead to severe hunger in the absence of food. For food-insecure ART patients, the additional appetite might be difficult to satisfy, which in turn, exacerbates their hunger. Inability of PLHIV, many of whom are already suffering from food insecurity, to satisfy increased appetite may discourage them

from taking their medications in order to avoid acute hunger. ART patients in SSA reported that ARVs increased their appetite and made them hungrier (Grant et al., 2008; Kalofonos, 2010; Nagata et al., 2012; Musumari et al., 2013; Weiser et al., 2010). Consequently, food-insecure ART patients who could not satisfy the extra appetite reported missing treatment doses in order to avoid intolerable hunger caused by taking ARVs on an empty stomach (Musumari et al., 2013; Weiser et al., 2010). Similarly, ART patients in SSA have cited their inability to buy additional food to satisfy their increased appetites and avoid hunger following treatment initiation as an important obstacle to ART adherence (Hardon et al., 2007; Murray et al., 2009; Sanjobo et al., 2008). For many ART patients, fear of hunger and food insecurity are enough to convince them to delay or discontinue treatment (Au et al., 2006). In sum, fear or actual experience of intolerable hunger caused by lack of food when receiving treatment is another pathway through which food insecurity prevents ART patients from adhering optimally to treatment.

Severe side effects. Side effects of ARV drugs can be exacerbated by inadequate food. Because food-insecure patients might not always have food to minimize the side-effects of ARVs, they might be forced to skip doses so as not to experience unbearable drug side-effects. Food-insecure ART patients in SSA experience worse side-effects, including severe forms of headaches, stomach pains, dizziness, tremors, fainting, and rapid heartbeat, when they take ARVs without food (Musumari et al., 2013; Nagata et al., 2012; Ware et al., 2009; Weiser et al., 2010). Conversely, PLHIV who take their medications with food experience no or mild side effects (Byron, Gillespie, & Nangami, 2008; Weiser et al., 2010). In other words, when access to food is limited, PLHIV might skip doses or discontinue treatment to avoid experiencing severe side effects of ARVS caused by not having adequate food. Further, severe side effects frequently interfere with people's day-to-day routine. For instance, severe side-effects might force PLHIV (even though they are not ill) to miss work days and earn less income, which in turn, heighten food insecurity. PLHIV may only take their pills when they have sufficient food, which in turn, compromises optimal medication adherence and better treatment outcomes. In sum, fear or

actual experience of side effects exacerbated by lack of food when taking ARV drugs is another pathway through which food insecurity prevents ART patients from adhering optimally to treatment.

Competing demands to meet food and treatment costs. Competing demands between costs of food and medical care might lead PLHIV to default from treatment and obtain food, or give up food and get medications (Gusdal et al., 2009; Weiser et al., 2010). PLHIV who struggle to meet daily food requirements and afford treatment-related costs at the same time may be compelled to choose either food or medicine. This dilemma is worsened by PLHIV's diminished capacity to earn income, which in turn, exacerbates food insecurity. Being on ART and paying for treatment-related costs (e.g., transportation to clinic or additional medications to prevent opportunistic infections) can intensify food insecurity when scarce financial resources are spent on treatment and medical care instead of food. Many ART patients in SSA have to either sacrifice food for themselves and their family to pay medical expenses, or they had to forego their medications in order to buy food (Gari, Martin-Hilber, Malungo, Musheke, & Merten, 2014; Gusdal et al., 2009; Weiser et al., 2010). Unlike households not affected by HIV, PLHIV and their households incur more and higher health-care expenses (Gregson et al., 2007; Kaler et al., 2010), which further deplete economic resources that can be used to purchase or produce food. Thus, the struggle to choose either food or treatment becomes more salient to poor HIV-affected households.

Medication diversion. In order to meet basic needs such as food, a growing body of evidence, albeit mostly in resource-adequate countries, suggests that PLHIV are selling or trading their medications or pills in the illicit market (Kurtz, Buttram, & Surratt, 2014; Surratt, Kurtz, Cicero, O'Grady, & Levi-Minzi, 2013; Surrat, O'Grady, Levi-Minzi, & Kurtz, 2015; Tsuyuki & Surratt, 2015), a practice commonly referred to as medication diversion. Obviously, medication diversion leads to fewer pills being taken by patients, which in turn, compromise full adherence to treatment recommendations. Although limited evidence on medication diversion

exists among PLHIV in SSA, medication diversion is a potential economic coping strategy that can be used by ART patients to cope with impoverishment and obtain food for themselves and their households. The lack of full ART coverage for all PLHIV in SSA might create a market that targets vulnerable ART patients who are willing to trade their medications for money and food.

Food insecurity and mental health. PLHIV have high levels of mental health burden (Bing et al., 2001; Fernandez & Ruiz, 2006; Komiti et al., 2003). Among food-insecure PLHIV, this mental health burden is exacerbated by food insecurity. For PLHIV in SSA, food insecurity contributes to poor mental health outcomes including depression (Tsai et al., 2012), perceived stress (Addo et al., 2011; Garcia et al., 2013), lower quality of life (Palermo, Rawat, Weiser, & Kadiyala, 2013), and suicidality (Kinyanda et al., 2012). In turn, poor mental health status negatively predicts ART adherence (Gonzales, Batchelder, Psaros, & Safren, 2011; Kidia et al., 2015; Langebeek et al., 2014). In other words, poor mental health may be another potential pathway to explain the relationship between food insecurity and treatment nonadherence. Unlike HIV negative individuals and food secure PLHIV, the co-occurrence of food insecurity and poor mental health status works together to weaken PLHIV's ability to adhere optimally to ART. Further, this pathway indicates a possible mediating role of mental health status on the relationship between food insecurity and ART adherence. However, few studies in SSA have examined the mediating role of poor mental health on food insecurity and treatment adherence. Most of what we know comes from studies that separately examined the relationship between food insecurity and mental health, and mental health and ART adherence.

In sum, several pathways illustrate how food insecurity interferes with ART adherence. The first three pathways focus on the biomedical explanations, and the last three covers the social and economic explanations. These pathways may affect motivation to adhere to treatment in spite of the knowledge of the benefits of ART. Overall, these pathways may explain why PLHIV skip doses or do not take their medications as prescribed when faced with inadequate access to food. Further, the current known pathways are not mutually exclusive and may overlap

with each other. It is possible that an ART patient skips doses frequently because of the belief that food is necessary to optimize treatment outcomes and severe side effects, including intolerable hunger, will occur when ARV drugs are taken without food. The co-occurrence of these pathways may greatly depress the ability of PLHIV to adhere to treatment when experiencing inadequate access to food. Although these pathways may exist simultaneously, more research needs to be done to examine which pathway (or co-occurrence of pathways) strongly predicts suboptimal adherence among ART patients in SSA. Currently, the literature provides little guidance on whether ART patients decide to skip doses because of severe side effects when medications are taken on an empty stomach, or because treatment will not be as effective without food, or because medications have been sold or traded for food. However, this list of potential pathways is not exhaustive. More research is needed to better understand and identify other mechanisms through which food insecurity contributes to suboptimal treatment adherence. For instance, lack of food may deprive PLHIV of the energy to travel to pharmacies to collect ARV drugs. However, limited empirical evidence is available to support this pathway. Future research should also begin to examine how food insecurity affects other dimensions of adherence such as schedule or timing. Nonetheless, the current known pathways contextualize the role of food insecurity in the lives of PLHIV and help us understand how lack of access to food contributes to ART patients' decision to skip doses, delay treatment or discontinue therapy.

Interaction of Food and ART Medications

ART is not required for all stages of HIV infection. The World Health Organization has instituted a revised guideline to determine when a person infected with HIV should begin ART (WHO, 2013). For instance, as a priority, ART should be initiated in all adults living with HIV with severe or advanced HIV clinical disease (i.e., WHO clinical stage 3 or 4), and individuals with CD4 count ≤ 350 cells/mm³. Once PLHIV begins ART, additional food and nutritional requirements are needed to manage the interaction of food and ARV drugs, improve efficacy of

ART through increased absorption and bioavailability² of drugs, and reduce severity of symptoms, including weight loss. ARV drugs may interact with food in at least three ways (FANTA 2004; Ivers et al., 2009). Figure 1 illustrates the three types of food-ART medication interactions.

First, food enhances absorption or metabolism of some ARVs and inhibits absorption or metabolism of other ARVs (Berginc, Trdan, Trontelj, & Kristl, 2010; Nerad et al., 2003; Raiten, 2011). In other words, some ARVs should be taken with food to increase drug efficacy, while other types of food should be avoided to prevent reduced drug efficacy and unhealthy side effects. Lack of food may impede optimal absorption of certain ARV medications, which in turn, may contribute to treatment failure (Bardsley-Elliot & Plosker, 2000; Nerad et al., 2003). For instance, evidence from Uganda suggests that food-insecure PLHIV have lower drug exposure and decreased bioavailability of ARVs contrasted with their food-secure counterparts (Bartelink et al., 2014). The effects of food on pharmacokinetics of ARV drugs may explain the association between food insecurity and poor clinical outcomes including incomplete viral suppression (Boffito et al., 2005; Sekar et al., 2007). Appendix A lists different ARV medications that are widely available in SSA and recommended food intakes and side-effects of ARV drugs.

Second, some ARVs can affect health and body composition outcomes by enhancing or inhibiting nutrient absorption, metabolism, and excretion (FANTA, 2004; Raiten, 2011). In Rwanda, for instance, some ARVs have led to lipoatrophy or fat loss (van Griensven et al., 2007). Further, changes in body shapes associated with ART may contribute to poor body image (Huang, Harrity et al., 2006; Huang, Lee et al., 2006) which negatively affects adherence (Duran et al., 2001; Plankey et al., 2009). Access to food may help prevent weight loss and reduce risk of lipoatrophy (van Griensven, Zachariah, & Mugabo, & Reid, 2010).

² Bioavailability refers to the proportion of a drug that enters the circulation when introduced into the body.

Third, ARVs may have side effects (e.g., nausea, vomiting, diarrhea, and taste changes) that negatively affect food intake and nutrient absorption (Beaugerie et al., 1998; de Pee & Semba, 2010). Better food intake and higher nutrient absorption prevent occurrence of adverse health outcomes including rapid deterioration of immune system and progression to AIDS (FANTA, 2004; Nerad et al., 2003; Weiser et al., 2011). ART patients may also experience increased appetite as a side-effect of ARV medications. Adequate food may alleviate medication side-effects, satisfy increased appetite, compensate for nutrient losses, and prevent hunger and weight loss, which in turn, can slow the progression of HIV to AIDS (Drain et al., 2007; FANTA, 2004; Piwoz & Preble, 2000).

In sum, adequate access to food, particularly access to a variety of nutritious food is critical for PLHIV who are receiving ART to manage the interactions between ARV medications and food. Lack of food may result in suboptimal treatment outcomes, severe side-effects, and treatment failure, which in turn, increase risk of mortality and morbidity. Although food and nutritional guidelines in resource-adequate and resource-limited settings are in principle not different, effective food and dietary management for ART patients in SSA may be more challenging to fulfill due to higher prevalence of food insecurity.

Effects of Adherence to ART

Although adherence is not the only predictor of treatment failure or success, adherence to ART is one of few potentially alterable factors that strongly influence outcomes for PLHIV. Optimal adherence is important because adherence predicts better health outcomes (Bangsberg, et al., 2001; Pasternak et al., 2012; Wood et al., 2003; Steele et al., 2011). Optimal adherence is associated with lower risk of mortality and increased rate of survival (Wood et al., 2006). Alternatively, nonadherence to ART is associated with higher risk of progression to AIDS and death (Bangsberg et al., 2001; Chi, Cantrell et al., 2009; Stringer et al., 2006). Optimal adherence is also associated with improved immunologic outcome (Mannheimer, Friedland, Matts, Child, & Chesney, 2002; Moore et al., 2006). Alternatively, nonadherence is associated

with immunologic failure or low CD4 count (Abrogoua et al., 2012; Chi, Cantrell et al., 2009; Wood et al., 2004). A low CD4 count increases the risk of AIDS- and non-AIDS-related mortality and morbidity (Chi, Giganti et al., 2009; Gupta et al., 2011; Hogg et al., 2001; Loutfy et al., 2005; Moore, et al., 2006; Weber et al., 2006). Alternatively, higher CD4 counts decrease risks of AIDS and non-AIDS-related diseases (Baker et al., 2008; Ledergerber et al., 1999; Monforte et al., 2008).

Optimal adherence to ART is also associated with improved virologic outcome or full viral suppression (Bangsberg et al., 2000; Mannheimer et al., 2002; Nachega et al., 2007; Pasternak et al., 2012). Alternatively, nonadherence to ART is associated with virologic failure³ or incomplete viral suppression (Bangsberg et al., 2000; Paredes et al., 2010; Spacek et al., 2006). Full or complete viral suppression leads to proper immune function and minimizes development of drug-resistant HIV. Further, low viral loads and viral suppression may reduce HIV transmission, which in turn, may lead to a decline in number of new HIV infections (Cohen et al., 2011). Low or undetectable viral load is also associated with reduced risk of AIDS-related opportunistic illnesses (Ledergerber et al., 1999). Finally, optimal adherence is associated with lower risk of developing resistance to ARV drugs (Hecht et al., 1998; Maggiolo et al., 2007; Yerly et al., 1999). Alternatively, nonadherence or missed doses is associated with antiretroviral drug resistance (Oyugi et al., 2007). The emergence of drug resistant HIV due to suboptimal adherence may result in transmission of drug-resistant virus. For instance, high rates of drug resistant HIV have been found in recently infected PLHIV including those who are not yet on ART (Grant et al., 2002; Little et al., 2002). The spread of drug-resistant strains of HIV means the infection cannot be effectively treated with ARVs that have been widely available in SSA. In addition, the progress that has been achieved to reduce HIV infection in the region would

³ Virologic failure refers to inability to achieve or maintain suppression of viral replication to an HIV RNA level < 200 copies/mL (NIH, n.d.).

encounter challenging setbacks with critical public health implications for effective HIV prevention in SSA.

Summary

The introduction of ART is among and continues to be one of the most important advances in the history of HIV/AIDS treatment (Broder, 2010). In particular, the expansion of ART in SSA has provided life-saving medications that transformed HIV from an acute, life-threatening illness to a chronic, more manageable condition. However the overlap between food-insecure PLHIV and ART patients may pose unanticipated challenges to the success of HIV treatment programs. In SSA, the HIV epidemic largely overlaps with populations already suffering from food insecurity. In many parts of SSA, the poor has been disproportionately affected by HIV/AIDS (de Waal & Whiteside, 2003; Whiteside, 2002). As more food-insecure PLHIV in SSA obtain access to ART, they may encounter difficulties adhering to treatment because of limited or lack of access to food. A growing body of qualitative and quantitative research in SSA suggests that food insecurity is a major barrier to ART adherence. Adequate food is important to ensure efficacy of ARV drugs, alleviate HIV-related symptoms and medication side-effects, prevent undernourishment and weight loss, and boost immune functioning to fight opportunistic infections. Lack of food may also lead to suboptimal adherence, which in turn, contributes to treatment failure. Although adherence is not the only predictor of ART failure or success, ART adherence remains one of few potentially modifiable factors that strongly influence a range of desirable outcomes for PLHIV. Given the clinical and public health consequences of suboptimal adherence, better understanding of the strategies used by PLHIV and their families to cope with food insecurity is needed. A thorough understanding of coping strategies within the context of reduced income, costly health care expenses, increased care-giving burdens, and stigma may inform stakeholders of appropriate and promising interventions.

Interventions for Food Security of PLHIV: Integrated with HIV Treatment

Interventions to promote food security (and positive health) of PLHIV can be classified into three general categories: food assistance (FA), integrated HIV and livelihood programs (IHLPs) and combined food and livelihood assistance programs (CFALPs). FA includes supplementary feed (or food rations) and therapeutic feeding. Whether an FA program represents supplementary or therapeutic feeding may depend on target population and/or program intent. Supplementary feeding is generally targeted to food-insecure and undernourished PLHIV and their dependents to provide adequate access to safe and nutritious food. Supplementary feeding is also viewed as a safety net program designed to improve household food security and mitigate adverse effects of HIV. Therapeutic feeding, on the other hand, targets severely malnourished PLHIV and provides them with specialized foods that are high in energy and nutrients for rapid nutritional rehabilitation before or during treatment. Therapeutic feeding is sometimes referred to as nutrition supplementation intervention. The two types of FA programs reflect a biomedical approach to addressing downstream consequences of food insecurity among PLHIV, particularly those who are receiving ART. On the other hand, IHLPs aim to address upstream causes of food insecurity, such as lack of income and assets. IHLPs are generally multifaceted economic-strengthening interventions that are linked with HIV treatment. IHLPs are varied and have historically included one or more of the following components: direct transfer of cash or assets, technical skills training related to a specific livelihood or employment, life or soft skills training such as financial literacy, access to financial services such as savings products and credit services, and access to health-related services and training such as nutrition counseling and medical treatment. Consistent with livelihood assistance programs for the general population, IHLPs are generally designed to increase household income and assets, provide employment, cope with economic shocks, and maintain consumption patterns for PLHIV and their households. Food assistance and livelihood programs have been previously implemented in the general population to increase food security.

In addition, a growing body of evidence indicates the growing popularity of food security programs to both address challenges related to inadequate access to food and suboptimal treatment behaviors that PLHIV encounter in their day-to-day lives. Further, a growing number of CFALPs have integrated food assistance as a short-term strategy with livelihood support as a longer term strategy to food security.

Food Assistance Programs

Consistent with programs for the general population, FA programs play an important role to curb acute food insecurity among the most vulnerable PLHIV. Although FA programs have historically targeted populations regardless of HIV status, recent programs have purposely expanded coverage to PLHIV because of the high prevalence of food-insecure PLHIV and importance of food on health and treatment-related outcomes for ART patients. In Zambia, for instance, the World Food Programme has been providing food support as part of HIV care and treatment programs in the country (Cantrell et al., 2008; Tirivayi, Koethe, & Groot, 2012; Zulu et al., 2011). Typically, food-insecure ART patients receive monthly food rations for six months, with the option to continue for an additional six months.⁴ All ART patients are eligible for food insecurity evaluation, while poor clinical nutrition status is not a requirement for enrollment (Tirivayi et al., 2012). Eligibility criteria for food assistance are based on poverty and HIV-related indicators, including household size and composition, number of HIV-affected household members, asset ownership, employment status, income, housing characteristics, education, and household dietary diversity (FANTA and WFP, 2007; Cantrell et al., 2008). A composite score based on the indicators is created; and ART patients with scores above a certain cutoff receive food assistance. Similar food assistance programs that are linked with HIV treatment have also been implemented in other parts of SSA, including Uganda (Rawat,

⁴ The monthly ration size is based on the number of people living in the household, with three-person household receiving an individual ration, whereas household with more than 3 people receive a ration sufficient for six adults (Cantrell et al., 2008). Individual monthly ration is comprised of maize (25 kg), vegetable oil (1.8 liters), peas (4.5 kg), and a corn and soy blend flour (6.0 kg; Tirivayi et al., 2012). Standard food basket provides approximately 1,100 kcal/d per person (Rawat et al., 2014).

Kadiyala, & McNamara, 2010; Rawat, Faust, Maluccio, & Kadiyala, 2014), Malawi (Bahwere, Sadler & Collins, 2009; Bowie et al., 2005), Mozambique (Posse & Baltussen, 2013; Ndekha, van Oosterhout, Zijlstra et al., 2009), and Kenya (Byron et al., 2008; Ndirangu et al., 2014), as well as in other resource-limited countries outside SSA (Ivers et al., 2014; Nyamathi et al., 2013; Palar et al., 2015; Swaminathan et al., 2010).

Impact of FA programs on treatment adherence and other health outcomes.

Evidence indicates mixed effects of FA programs on health outcomes of ART patients in SSA (Audain et al., 2015; Rawat et al., 2014; Tirivayi & Groot, 2011). Most studies have found positive effects of FA programs on treatment adherence (Audain et al., 2015; de Pee, Grede, Mehra, & Bloem, 2014). In Zambia, for instance, receipt of regular food aid was associated with higher ART adherence (Cantrell et al., 2008; Tirivayi et al., 2012). Similar findings were observed in FA programs for PLHIV in Mozambique (Posse, Tirivayi, Saha, & Baltussen, 2013), Niger (Serrano et al., 2010), and countries outside SSA (Martinez et al., 2014, Ivers et al., 2014). However, in Malawi, FA programs did not significantly increase treatment adherence levels (Ndekha, van Oosterhout, Zijlstra et al., 2009; van Oosterhout et al., 2010).

Studies have also consistently found positive effects of FA programs on weight and body mass index (BMI) of ART patients in SSA (Ahoua et al., 2011; Audain et al., 2015; Olsen et al., 2014; Rawat et al., 2010; van Oosterhout et al., 2010). Further, FA programs decrease household food insecurity (de Pee et al., 2014; Rawat et al., 2014). However, FA programs have inconclusive effects on other outcomes such as markers of disease progression (e.g., CD4 count) and quality of life (Audain et al., 2015; Cantrell et al., 2008; Rawat et al., 2014; van Oosterhout et al., 2010). Nonetheless, program participants have positive views about the benefits of FA programs on their wellbeing. FA recipients have consistently mentioned that food assistance helped them achieve better health and treatment outcomes, including regular access to food and better nutrition, greater motivation to collect their medications, and improved ART adherence (Ndirangu et al., 2014; Posse & Baltussen, 2013).

The mixed findings may suggest that one type of FA programs (those that offer ready-to-use therapeutic food or RUTF) may work well for achieving certain outcomes (for example, higher BMI and weight gain), while other FA programs (those that offer regular food aid) may work well for achieving different outcomes (for example, ART adherence). More research is needed to determine: 1) the type of FA program that is more effective in achieving positive health outcomes, particularly ART adherence; 2) the optimal duration of FA programs; 3) the subgroup of PLHIV who may benefit the most from different FA programs; 4) the long-term or sustainability of effects of FA programs on health and treatment outcomes of ART patients; and 5) coping strategies of PLHIV and their households after the end of food supplementation. For instance, PLHIV with advanced disease stage and severe immunosuppression may benefit more from RUTF or nutrition supplementation programs because advanced HIV disease is characterized by acute weight loss and wasting, and the potential benefits may be greatest for these individuals. Regular food aid or safety net programs may benefit food-insecure PLHIV who have recently started ART by providing them incentives to regularly collect medication and incorporate ART adherence into their daily routine. Safety net programs may also help clinically-stable PLHIV to improve their health and regain energy, which in turn, may help them begin or continue income-generating activities and increase household food security. In addition, it is important to identify whether effects of FA programs are sustained subsequent to food supplementation or after the end of FA receipt. Because PLHIV have to take their medications for a long period of time, interventions must also be able to sustain or maintain positive effects beyond the duration of the program. Preliminary evidence suggests that the effects of FA interventions (including improvement in ART adherence) were not sustained after the end of the program (Ndekha, van Oosterhout, Salojee, Pettifor, & Manary, 2009; Ndirangu et al., 2014). This finding may suggest that continuous food supplementation may be necessary to maintain positive health and treatment-related effects.

Integrated HIV and Livelihood Programs

Recognizing that food assistance programs do not address the root causes of food insecurity and have limited scope in sustaining benefits, an increasing number of HIV treatment programs have been linked with livelihood activities for ART patients. A livelihood, which is defined as set of capabilities, assets and activities required for means of living (Chambers & Conway, 1991), serve as a social and economic strategy to mitigate the adverse impacts of HIV, poverty and food insecurity on the wellbeing of PLHIV. In addition, livelihood programs may complement behavioral and biomedical interventions in fostering positive health, including better HIV treatment outcomes among PLHIV. Consistent with the definition of livelihood, livelihood interventions that have been integrated with HIV programs cover a broad set of activities designed to strengthen household economic security (Aberman et al., 2014; Kennedy, Fonner, O'Reilly, & Sweat, 2014).

With food security as an outcome, a livelihood approach focuses on understanding, identifying and promoting people's means of achieving food security, particularly through income generation and asset accumulation. While the design of IHLPs varies, these programs support investment in various income-generating activities such as small-scale agriculture, livestock-raising, craft-making, or retail. In many cases, income-generating activities are specific to local needs and economic conditions. Consistent with livelihood programs for the general population, IHLPs provide ART patients with access to various technical and life skills training, farming and livestock input and materials, and financial products and services such as loans and savings. For instance, a pilot agricultural intervention for food security and HIV treatment outcomes in Kenya included: 1) a microfinance loan to purchase a low-cost micro-irrigation pump which allows farmers to irrigate crops year-round; 2) agricultural training on how to use the pump, prepare the fields, and plant seed beds; and 3) irrigation and farming materials such as pipes, seeds, fertilizers, and pesticides (Pandit et al., 2010). The program aimed to help HIV-positive farmers establish small agricultural businesses. Further, many

IHLPs encourage group formation to build social capital among participants and provide psychosocial support for each other as a way to alleviate the adverse effects of stigma and discrimination on the social, economic, and psychological welfare of PLHIV (Kadiyala, Rawat, Roopnaraine, Babirye, & Ochai, 2009; Roopnaraine, Rawat, Babirye, Ochai, & Kadiyala, 2012).

Recent evaluations of livelihood programs for the general population have shown positive impacts on a broad range of desirable outcomes, including higher per capita consumption, household food security, increased income, more assets, and improved mental health (Banerjee et al., 2015; Banerjee & Duflo, 2011). Livelihood approaches have also been shown to reduce risk of HIV infection through engagement in more HIV-protective behaviors (Hardee, Gay, Croce-Galis, & Peltz, 2014; Kennedy, Fonner, O'Reilly, & Sweat, 2014; Pronyk et al., 2008). Although livelihood programs have been commonly employed as an antipoverty strategy in the general population, these programs have not been widely implemented and rigorously evaluated to determine impacts on poverty and economic (including food) security among PLHIV and their households. Similarly, limited evidence exists on the effects of livelihood programs on health and treatment-related outcomes of ART patients.

In SSA, food assistance programs remain more commonly integrated with HIV treatment than livelihood interventions (Aberman et al., 2014; Anema et al., 2012; de Pee et al., 2014). Nonetheless, a growing number of IHLPs have been implemented in SSA including Cote d'Ivoire (Holmes, Winskell, Hennink, & Chidiac, 2011); Kenya (Cohen et al., 2015; Datta & Njunguna, 2008; Pandit et al., 2010), and Uganda (Wagner, Rana, Linnemayr, Balya, & Buzaalirwa, 2012). Similar programs for ART patients have also been put in place in Malawi, Mozambique and Namibia (FANTA & WFP, 2007; McCaston, Berkowitz Nchabeleng, van der Land, Fowler, & Brand, 2010). These programs targeted HIV-affected households regardless of whether household members were receiving ART or not. However, as access to ART in SSA continues to rise and more PLHIV begin treatment, the number of IHLPs may also increase as more ART patients regain strength and require assistance to (re) start a livelihood.

Impact of IHLs on adherence and health outcomes. Although studies have demonstrated feasibility of livelihood programs for PLHIV on ART (Datta & Njuguna, 2009; Holmes et al., 2011; Pandit et al., 2010), few IHLs have been rigorously evaluated. Compared with FA programs, the evidence base of IHLs is limited and the quality of causal evidence is weak. Preliminary and qualitative evidence suggests positive impact of IHLs on household income and food consumption (Pandit et al., 2010; Wagner, Rana et al., 2012). Qualitative evidence also indicates that IHLs reduce stigma and increase PLHIV's sense of dignity, self-worth and standing in the community (Holmes et al., 2011; Holmes & Winskell, 2013; Wagner, Rana et al., 2012). However, little is known about the effects of IHLs on health outcomes of PLHIV, including adherence to ART. Further, few IHLs have been able to empirically support the pathways in which a livelihood program for PLHIV may impact food security and health outcomes (Kadiyala et al., 2009). More rigorous intervention studies are needed to understand and identify potential mechanisms in which IHLs may affect food security and treatment adherence, as well as other HIV treatment-related outcomes. Similarly, more studies are needed to test and evaluate which markers of HIV disease – viral load, CD4 count, clinical stage, or adherence – are most relevant to accurately examine the impact of IHLs on health outcomes. Further research is also needed to examine whether IHLs' impact differ depending on program design and components. Because IHLs can include several types of economic training and activities, it is critical to determine the comparative effect of different IHLs, and if possible, the optimal combination of livelihood activities that maximizes potential impacts on food security and ART adherence. For instance, small-scale agricultural and livestock programs may be more effective in reducing food insecurity because they directly affect food production. A livelihood program that includes cash transfers or loans may be beneficial as cash can be used to purchase food before income is generated from livelihood activities. In sum, development and implementation of IHLs have outpaced research and evaluation of potential effects on PLHIV's health, including adherence to ART.

Combination Food Assistance and Livelihood Programs

The third type of intervention for food security and ART adherence combines food assistance and livelihood programs with HIV treatment. This type of intervention provides food assistance to ART patients, right before or immediately after ART initiation. In addition to food assistance, ART patients receive livelihood training assistance either during or immediately after the food supplementation phase. CFALPs are designed to address the immediate food needs of ART patients in order to optimize treatment outcomes and avoid adverse treatment effects. CFALPs are also designed to ensure a more sustainable access to food in order to maintain positive effects of food security on health and wellbeing of ART patients.

Although CFALPs target both immediate and long-term food insecurity, CFALPs are the least common intervention (of the three: FA, IHLP and CFALP) implemented in SSA. A review of the literature yielded one example of CFALP in SSA – the Academic Model Providing Access to Health (AMPATH). AMPATH is one of the first HIV care programs in SSA to implement a comprehensive HIV treatment program with food supplementation and livelihood support for food-insecure ART patients and their dependents (Mamlin et al., 2009). A unique feature of AMPATH is its creation of high-production farms to complement its food supply from donation and purchase. The farms are also used to teach AMPATH patients how to increase crop yield in their own land (Byron et al., 2008; Mamlin et al., 2009).

All newly registered AMPATH patients are assessed for food support eligibility based on clinical and socioeconomic indicators (Byron et al., 2008). Depending on the level of need, the program may provide up to 100% of caloric needs for the patient and dependents (Mamlin et al., 2009). All food-insecure patients and their household dependents are provided food assistance for six to 12 months. Before the end of food support, patients are transitioned to another program, named Family Preservation Initiative (FPI). FPI assists patients who graduated out of the food support program with knowledge-building and skills training in income generation. FPI provides training on several livelihood activities (e.g., small agri-business) and business

management, as well as access to microcredit and agricultural technical support to improve farming or husbandry techniques (Byron et al., 2008).

Impact of CFALPs on adherence and health outcomes. Limited data are available to examine the effects of CFALPs on adherence and other health outcomes of ART patients in SSA. Qualitative evidence suggests positive benefits of AMPATH's FA program on food security and body composition of PLHIV (Byron et al., 2008). However, the impact of AMPATH's FPI program or combined FA and FPI program on food security, ART adherence, and other ART-related outcomes is not known. More impact evaluation of CFALPs is needed to address current research gaps and inform integrated HIV and economic policy and practice in resource-limited settings.

Analysis of Interventions for Food Security and ART Adherence

Each intervention for food security and ART adherence has its own strengths and limitations. For instance, FA programs have been documented to positively impact ART adherence and health outcomes such as weight and BMI. On the other hand, limited evidence exists on the impacts of IHLPs and CFALPs on ART adherence and related outcomes. Beyond the evidence base, the three current interventions differ based on program design, program effectiveness, and potential effects beyond food security. Table 1 summarizes the strengths and limitations of each intervention based on multiple program design and impact indicators. Appendix B discusses the strengths and limitations of the three interventions.

Summary and Implications for Research

Because of the importance of food to health and well-being of PLHIV in general and to optimal ART adherence in particular, interventions, both at the individual and household-level have been implemented to address food insecurity among PLHIV. Food security interventions for PLHIV share similarities with food and livelihood assistance programs for the general population. However, interventions for PLHIV may require a different approach given health conditions of PLHIV and food and nutritional demands of HIV and ART. For instance,

livelihood programs that are labor intensive may not be appropriate for ART patients with limited strength, whereas FA programs may be preferable for undernourished ART patients because immediate access to food helps rehabilitate nutrition and increase weight. Although standalone FA and IHLs may benefit PLHIV, a combination of FA and livelihood activities as a continuum of care may be a more effective way to achieve long-term food security and optimal treatment adherence. FA programs may be beneficial for nutritional rehabilitation of PLHIV and allow patients to regain strength and energy while adhering to treatment. As PLHIV live longer and healthier lives, they may need programs that offer opportunities to start a livelihood, which in turn, provides a more stable access to food. With adequate access to food at all stages of ART, PLHIV may be less likely to delay start of treatment, skip taking medications, interrupt treatment, or prematurely drop out of ART programs.

However, in order to meaningfully contribute to the betterment of PLHIV's life and maximize scarce resources, interventions need to be implemented with fidelity and rigorously evaluated to provide evidence of efficacy and effectiveness. Although FA and IHLs have been implemented and shown to be feasible with PLHIV, research has not caught up with practice. Of the three interventions, FA remains the only one that is evidence-based and has been shown to positively impact ART adherence. Two major gaps in knowledge exist. First, little is known on whether a combination intervention of FA and livelihood may lead to better health outcomes, including ART adherence. Most of the published studies are either FA or IHL only. Second, there is limited evidence on the impacts of livelihood programs on treatment adherence and other health outcomes. This critical gap in knowledge exists because: 1) a small number of livelihood programs have specifically targeted food-insecure PLHIV and been integrated with HIV treatment; 2) the growing number of IHLs, particularly in SSA, has not been consistently and rigorously studied; and 3) the few IHLs that have been systemically evaluated did not include ART adherence as an outcome measure. More research is needed to address these gaps. In addition, rigorous evidence is essential to inform policy and practice decisions that best

address the synergistic relationship of food insecurity and poor HIV treatment outcomes in resource-limited settings.

Background Information on Zambia

Geography

The Republic of Zambia is a landlocked country in Southern Africa. Zambia is the world's 39th largest country in terms of land area, covering 752,612 square kilometers. Comparatively, Zambia is slightly larger than the state of Texas. About 58% of Zambia's total land area is classified as having medium to high potential for agricultural production, but less than half of arable land is cultivated (Central Statistical Office [CSO], 2012b). Zambia borders eight countries: the Democratic Republic of Congo to the north; Tanzania to the northeast; Malawi to the east; Mozambique, Zimbabwe, Botswana, & Namibia to the south; and Angola to the west. Zambia shares its longest border with the Democratic Republic of Congo, with 2,332 kilometers of shared border. The country's climate is tropical. Rainy season runs from October to April.

Political Organization and Governance

The Republic of Zambia gained its independence from the United Kingdom in 1964. Zambia is a constitutional democracy that has three branches of government: executive, legislative and judicial. The president acts as both chief of state and head of government. The legislative branch is composed of a unicameral National Assembly with 158 seats. The country's highest court is the Supreme Court which consists of the chief justice, deputy chief justice and seven justices. Administratively, the country is divided into ten provinces: Central, Copperbelt, Eastern, Luapula, Lusaka, Muchinga, Northern, North-Western, Southern and Western. The ten provinces are further subdivided into 90 administrative districts. Lusaka is the largest city and the country's seat of government. Figure 2 shows the map of Zambia by provincial boundaries and bordering countries.

Population and Society

As of 2010, Zambia has a population of 13,093,000 (CSO, 2014). The country's population density is 17.4 persons per square kilometer (CSO, 2012a). Over 65% of the population lives in rural areas (CSO, 2012b). The country has a young population, with 74% of the population aged 30 and below. Fifty-one percent of Zambians are female. The country's population is characterized by high ethnic and cultural diversity. There are 73 ethnic groups with distinct cultural and linguistic characteristics. The major ethnic groups in the country include Bemba (21% of the population), Tonga (14%), Chewa (7%), Lozi (6%), Nsenga (5%), Tumbuka (4%), and Ngoni (4%) (CSO, 2012a). Besides English, which is the official language, Zambia has seven major languages: Bemba, Kaonde, Lozi, Lunda, Luvale, Nyanja and Tonga. Bemba is the predominant language of communication, with 3.7 million speakers (CSO, 2012a). Nyanja and Tonga have more than 1.2 million speakers.

In 2010, the total number of households in Zambia was 2,491,000. Overall, average household size was 5.2. Urban and rural households had similar household sizes. Female-headed households were slightly smaller (4.2) than male-headed households (5.1). Twenty-three percent of all households were female headed. Further, 54% of the population was married. Women are getting married at a younger age than men. In particular, 49% of women between 20 and 24 years old were married contrasted with 18% of men in the same age group (CSO, 2012a).

Economy and Labor

The World Bank classifies Zambia as a lower middle income country, with a per capita income of 1,810 USD in 2013. The country's economy is dominated by two industries – mining and agriculture. Zambia's main export is copper which accounts for 70% of the country's export. However, majority of the population (estimated at 65%) is dependent on subsistence agriculture for livelihood (CSO, 2012b).

In 2010, 62% of the total population aged 12 years and above were in the labor force. The proportion of the population who were economically active declined slightly from 65% in 2006 to 62% in 2010. Among those in the labor force, 43% were in paid employment, 11% were unpaid family worker, and 8% were unemployed. A higher percentage of rural (46%) than urban (38%) residents was in paid employment. Further, unemployment was higher among urban (16.3%) than rural (3.3%) residents. Women (59%) had lower labor force participation rates than men (66%). Urban women had the lowest labor force participation rates – at 48%. Urban and rural men and rural women had similar labor force participation rates – at 66% (CSO, 2012b).

Among those who were in paid employment in 2010, 67% were employed in agriculture and agriculture-related industries. Other major industry employers were retail (10%), community and social services (9%), and manufacturing (3%). In 2010, the mining industry employed less than 2% of all employed Zambians. The major industry employer in rural areas is agriculture, whereas retail is the major industry employer in urban areas. In 2010, 87% of paid rural employees worked in agriculture, while 27% of paid urban employees worked in the retail industry. Similarly, the most common type of occupation in Zambia is skilled agricultural and fishery work, followed by retail and service work. By employment status, 54% of employed Zambians were self-employed in 2010. Ten percent were private sector employees, and 6% were national government employees. A significant portion of the Zambian labor force is engaged in the informal sector.⁵ In 2010, 83% of Zambians were employed in the informal sector. Women (90%) were more likely to work in the informal sector than men (76%). Similarly, rural residents (92%) were more likely to earn income from the informal sector than urban residents (58%). Most workers in informal employment are in agriculture. In 2010, 77% of “informal workers”

⁵ Informal sector employment is defined as employed where the employed individual was: a) not entitled to paid leave; b) not entitled to pension, gratuity or social security; and c) working in an establishment that employs five persons or fewer (CSO, 2012b).

worked in agriculture. Not surprisingly, more rural residents (90%) were engaged in informal agriculture work than urban residents (21%; CSO, 2012b).

Poverty and Inequality

Poverty remains high in Zambia, with 60% of the population living in poverty (CSO, 2012b, 2012c). Among those in poverty, 42% are in extreme poverty (CSO, 2012b). Poverty is more prevalent in rural than urban areas – with 78% of rural residents living in poverty compared with 28% of urban residents (CSO, 2012b, 2012c). Poverty rates increase as household size becomes larger. In 2010, 66% of households with at least seven members were living in poverty and 47% were living in extreme poverty. However, 54% of households with four or less members were living in poverty and 34% were living in extreme poverty.

Zambia has a human development index (HDI) value of 0.561, which is higher than the HDI values of Zambia's neighboring countries except Botswana and Namibia.⁶ In terms of wealth, rural residents own substantially less wealth than their urban counterparts. Contrasted with 48% of urban residents, only 2% of rural residents belong to the highest wealth quintile (CSO, Ministry of Health [MoH], & ICF International, 2015). In addition to income and asset poverty, food insecurity remains widespread. Six million people (or approximately 43% of the population) were food insecure and undernourished during 2011 to 2013 (FAO et al., 2013). Food insecurity is prevalent in both urban and rural areas. However, rural residents are at a higher risk of food insecurity due to their dependence on subsistence farming and crops that are vulnerable to flood and drought (Kodamaya, 2011).

Although the country has been experiencing economic growth for the past several years, the positive effects of economic growth on household income have not been felt by all

⁶ The Human Development Index measures the social and economic development of a country. HDI includes three dimensions of human development – health, education, and standard of living. HDI combines four major indicators: life expectancy at birth, expected years of schooling, mean years of schooling, and gross national income per capita. The scores for the dimensions are aggregated into a composite index. Higher HDI values indicate higher levels of human development (United Nations Development Programme [UNDP], n.d.).

households, particularly lower income households. For instance, the poorest 50% of the population accounted for 9% of the country's per capita income in 2010. On the other hand, the richest 10% of the population made 53% of the country's per capita income in 2010. Income inequality, as measured by the Gini coefficient, increased from 0.60 in 2006 to 0.65 in 2010.⁷ Income inequality patterns differ between rural and urban areas. Income inequality in rural areas increased from 0.54 in 2006 to 0.60 in 2010. On other hand, income inequality in urban areas decreased from 0.66 in 2006 to 0.60 in 2010 (CSO, 2012b).

Household Income and Expenditure

Increasing household income remains an important component of the country's poverty alleviation strategies. Accordingly, income is used commonly to evaluate progress or impacts of government antipoverty policies and programs. In 2010, the average monthly income for Zambian households was 1,112,000 ZMK or roughly 214 USD.^{8,9} Urban households tend to have higher income than their rural counterparts. In 2010, average monthly income for urban households was 1,917,000 ZMK (or 369 USD) compared with 664,000 ZMK (or 128 USD) for rural households. More than half (57%) of all Zambian households earned an average monthly income of 600,000 ZMK (roughly 116 USD) or less in 2010. This amount translates to an average of less than 4 USD per day, or less than 1 USD per day per household member for a household with a typical household size of five. Further, male-headed households earned, on average, 327,000 ZMK (roughly 63 USD) more than female headed households. Real monthly

⁷ The Gini coefficient measures the extent to which income distribution among individuals or households within an economy deviates from a perfectly equal distribution. The coefficient ranges between 0 (which means everyone earns the same) and 1 (which means one person earns all the income). The Gini coefficient is a widely used measure of income inequality.

⁸ Household monthly income refers to all income from all sources of all income-earning members of the household (CSO, 2012b).

⁹ Beginning January 1, 2013, the Bank of Zambia rebased the Zambian currency (kwacha). The new Zambian kwacha was introduced at a rate of 1,000 old kwacha (ZMK) = 1 new kwacha (ZMW). All income and other monetary data prior to 2013 are quoted in the old Zambian kwacha. All income and other monetary data cited on or after January 1, 2013 are listed in the new Zambian kwacha.

per capita income in the country increased from 154,000 ZMK in 2006 to 269,000 ZMK in 2010. In 2010, urban households also had a higher level of per capita income (470,000 ZMK) than their rural counterparts (158,000 ZMK; CSO, 2012b).

Household monthly expenditures vary based on geographic residence and type of goods and services. In general, urban households have higher expenditures than rural households. In 2010, urban households spent 1,723,000 ZMK (or approximately 332 USD) per month on food and non-food items contrasted with rural household's monthly expenditure of 551,000 ZMK (or approximately 106 USD). Further, rural households spend more on food as a proportion of their total monthly expenditures contrasted with urban households. In 2010, 65% of rural households' monthly expenditures were spent on food items contrasted with 39% of urban households' monthly expenditures. Finally, the percentage of household food expenditures increased from 42% in 2006 to 49% in 2010 (CSO, 2012b). This increase may be explained by higher food prices and/or positive changes in household size.

Household Food Production and Food Availability

Agricultural activities such as food crop growing, livestock and poultry-raising, and fish farming contribute to household food security. In addition, agricultural activities provide a source of income for many households in Zambia. In 2008/2009 agricultural season, 66% (or 1,631,000) of all Zambian households were considered agricultural households, i.e., at least one household member was engaged in crop growing, livestock and poultry raising, fish farming or a combination of any of these activities. Although the absolute number of agricultural households in the country increased slightly from 1.5 million in 2006 to 1.6 million in 2010, the proportion of agricultural households decreased slightly from 68% in 2005/2006 season to 66% in 2008/2009 season. Further, nine in 10 rural households were considered agricultural contrasted with two in 10 urban households (CSO, 2012b).

Maize, which is a staple of the Zambian diet, remains the most commonly grown food crop in the country. In 2008/2009 season, 2 million metric tons of maize was produced in the

country. Eighty-three percent of all agricultural households grew maize in the 2008/2009 season. Most maize production occurs in rural areas, with 84% of all rural households producing 1.8 million metric tons. Other commonly-grown crops include groundnuts, cassava, sweet potatoes, and mixed beans. Compared to the 2005/2006 season, food crop production in Zambia increased in 2008/2009 season (CSO, 2012b).

The number of agricultural households that owned livestock increased from 422,000 in 2006 to 588,000 in 2010. Of the 588,000 livestock-owning households in the country, 95% were rural households. Five in ten agricultural households owned a cattle or goat. In 2008/2009 season, there were 2.6 million cattle, 2.1 million goats, and 0.8 million pigs in the country. Consistent with crop growing, livestock-raising is concentrated primarily in rural areas. In 2010, for instance, 94% of cattle, goats and pigs were raised in rural areas. With the exception of cattle, the number of livestock in the country increased from the 2005/2006 season to 2008/2009 season (CSO, 2012b).

Compared with livestock (i.e., cattle, goat, pig and sheep), poultry (i.e., chicken, duck, goose, and guinea fowl) is more commonly owned by agricultural households. In 2010, nearly all (>98%) agricultural households owned a poultry. Poultry-raising was widespread in both rural (99% of agricultural households) and urban (94%) areas. In 2008/2009 season, there were 14.4 million chickens, 0.4 million ducks/geese, and 0.3 million guinea fowls raised in the country. More than 74% of all poultry-raising were in rural areas. However, the number of poultry in the country declined from the 2005/2006 season to 2008/2009 season. For instance, the number of chicken decreased by more than 1.5 million – from 15.9 in 2005/2006 to 14.4 in 2008/2009 (CSO, 2012b). As illustrated by data on household food production, food is produced and available in Zambia. These data suggest that food insecurity issues in the country may affect access to food more than food availability.

Health Services and Facilities

In Zambia, health services are delivered through five different types of health facilities. From largest to smallest based on size of catchment population, these facilities are level 3 hospitals ($\geq 800,000$), level 2 hospitals (200,000 – 800,000), level 1 hospitals (80,000 – 200,000), health centers (10,000 – 80,000), and health posts ($< 10,000$). Eighty-eight percent of health facilities in Zambia are government-owned, 13% are private health facilities, and 6% are faith-based facilities (MoH, 2013). The providers also differ in terms of available health services. For instance, health posts offer basic first aid services and serve sparsely populated areas. Health centers (which are located in both urban and rural areas) serve as primary care centers in the country. Level 1 or district hospitals offer general medical, surgical, obstetric, and diagnostics services; and support all referrals from health centers. Level 2 or provincial hospitals serve as referral centers for level 1 hospitals; and provide services in internal medicine, general surgery, pediatrics, obstetrics and gynecology, intensive care, psychiatry, and dental care. Level 3 or tertiary hospitals act as referral centers for level 2 hospitals; and offer specialty services in internal medicine, surgery, pediatrics, obstetrics and gynecology, intensive care, psychiatry, training, and research (MoH, 2013).

A survey conducted in 2009/2010 showed that 57% of Zambians who reported illness sought medical consultation. A slightly higher percentage of urban residents (60%) who became ill sought medical attention contrasted with their rural counterparts (56%). Among those who consulted a health facility, majority of them (53%) went to a government health centers, followed by government hospitals (30%), and faith-based health facilities (6%). In 2010, the average amount spent on medication and/or medical consultation was 20,125 ZMK (nearly 4 USD). On average, urban residents (30,196 ZMK or 6 USD) spent more on medication and related expenses than rural residents (13,090 ZMK or < 3 USD; CSO 2012b).

HIV and Treatment

Zambia has a generalized HIV epidemic, that is, HIV spreads throughout the population contrasted with being concentrated in specific high-risk populations (such as sex workers, injection drug users, and men who have sex with men). In 2013, Zambia's HIV prevalence (among adults 15 to 49 years old) was estimated at 12.5% (lower estimate = 11.9%; upper estimate = 13.3%), more than 100% higher than the prevalence rate in SSA, at 5.6% (UNAIDS, 2014). Of the estimated 1.1 million people living with HIV in the country, 87% (or 960,000) are 15 years and older. Women account for 52% (or 500,000) of PLHIV 15 years and older. Unprotected heterosexual activities remain the primary mode of HIV transmission – about 90% of new infections (National AIDS Council [NAC], 2014a). Risky sexual behaviors, for example, multiple and concurrent sexual partnerships, and low and inconsistent condom use, persist as key predictors of HIV acquisition. Although the level of HIV epidemic is higher in urban areas than rural areas, more rural residents are living with HIV because more Zambians live in rural than urban areas.

However, notable progress has been made in the country's drive to eliminate HIV/AIDS. For instance, estimated new adult HIV infections decreased substantially from 68,000 in 2005 to 42,000 in 2013 (UNAIDS, 2014). Further, access to ART and follow-up treatment visits continue to rise. An estimated 55% (or 530,702) of all adults living with HIV are receiving ART (UNAIDS, 2014). ART patient visits increased rapidly by 279% from 2006 to 2010 (Institute for Health Metrics and Evaluation [IHME], 2014). Health facilities in Zambia can accommodate further increases in ART visits given current facility resources. For instance, level-1 or district hospitals could increase average annual ART visits by 211% (IHME, 2014). These findings suggest that the country's health facilities are capable of providing universal access to HIV/AIDS treatment and care. However, progress in treatment and care provision has not always translated into lower mortality rate among PLHIV in the country (Rathod et al., 2014; Stringer et al., 2006). Data from the National AIDS Council indicate that 23% of PLHIV enrolled on ART

did not survive after 12 months, 33% after 24 months, and 51% after 60 months (NAC, 2014a). Timely HIV testing, early diagnosis, and patient adherence and retention remain key challenges that negate treatment benefits and decrease survival rates.

CHAPTER 2: THEORIES AND CONCEPTUAL FRAMEWORK, PROGRAM MODEL AND RESEARCH QUESTIONS

Theories and Conceptual Framework

Theories are useful to guide our understanding of why and how a particular issue occurs. Using several theoretical models, this chapter attempts to explain the relationship between food insecurity and ART treatment adherence. These theoretical models are applied to illustrate how and why food insecurity can contribute to suboptimal ART adherence among ART patients in SSA. Each theoretical model represents a particular level of understanding health behavior. First, the health belief model explains the influence of individual beliefs as motivators and predictors of health behaviors. Second, social cognitive theory describes the influence of psychosocial or interpersonal dynamics on health behaviors. Third, the conservation of resources theory explains the role of environmental factors (in particular, presence or absence of resources) on an individual's internal processes related to health behaviors. Fourth, memberships theory of poverty illustrates the influence of group factors and structural constraints on individual social and economic outcomes. Fifth, the information-motivation-strategy model is a theoretical framework that combines key propositions from the four theories and that informs intervention development through identification of three distinct and potentially alterable mechanisms that predict health behavior change. Finally, I propose an integrated conceptual framework that borrows relevant constructs from the five theoretical models and that integrates different levels of understanding the relationship between food insecurity and ART treatment adherence.

Health Belief Model (HBM)

HBM is a theoretical model of individual health behavior. HBM emphasizes the role of an individual's perceptions in choosing and carrying out a particular health behavior (Rosenstock, Strecher, & Becker, 1988). As a value-expectancy model (Ajzen, 1988; Fishbein & Ajzen, 1975), HBM recognizes that behavior (in this case optimal adherence to ART) is a function of the subjective value of an outcome (in this case desire to live a longer and healthier life in spite of being HIV positive) and of the subjective probability (or expectation) that a particular action (in this case adherence) will achieve the outcome (Janz, Champion, & Strecher, 2002; Rosenstock et al., 1988). HBM has been used to explain a range of health behaviors, including ART adherence in resource-adequate (Malcolm, Ng, & Rosen, & Stone, 2003) and resource-limited settings (Roura et al., 2009; Wringe et al., 2009). Few studies have used HBM to explain the relationship between a particular barrier to adherence (in this case food security) and ART.

HBM classifies an individual's perceptions, which predict health behaviors, into several dimensions. In particular, HBM posits six dimensions of interrelated beliefs (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy, and cues to action; Rosenstock et al., 1988) that influence health behaviors. Contrasted with a uni or bidimensional model, which is common in other intrapersonal theories of behavior change such as theory of planned behavior/reasoned action and protection motivation theory, HBM posits that an individual's ability to engage in a particular health behavior is determined by an interrelated set of beliefs. Further, by categorizing perceptions into distinct constructs, HBM provides more insight into which dimensions better predict health outcomes.

Although HBM has several constructs that are relevant in explaining the relationship between food insecurity and treatment adherence, two constructs – perceived barriers and perceived self-efficacy – are particularly salient to our understanding of why food insecure PLHIV are less likely to optimally adhere to ART. People's perception of the barriers to a

particular health behavior has been shown to be a strong predictor of actual behavior (Janz & Becker, 1984), including condom use to prevent HIV infection (Asare, Sharma, Bernard, Rojas-Guyler, & Wang, 2013; Volk & Koopman, 2001). Perceived barriers refer to costs (both monetary and nonmonetary) that must be overcome in order for an individual to perform a particular health behavior (Janz et al., 2002). In the case of ART adherence, numerous barriers both monetary (for example, lack of income) and nonmonetary (for example, quality of patient-provider relationship) contribute to suboptimal adherence (Lankowski et al., 2014; Mills et al., 2006; Reda & Biadgilign, 2012). In addition, a major cost or perceived barrier to optimal ART adherence particularly in SSA is food insecurity (Hong et al., 2014; Singer et al., 2015; Weiser et al., 2010; Young et al., 2014). If PLHIV on ART are food insecure, they may not be able to adhere to treatment optimally because lack of access to food may compel them to skip taking medications as prescribed or to take medications only when they have food. Based on the HBM, food-insecure ART patients weigh expected effectiveness or benefits of ART adherence against perceptions that taking ARV drugs without food is less efficacious and creates intolerable side effects, including severe hunger, exacerbated by lack of food. ART patients may also weigh expected benefits of ART against the belief that paying for treatment-related costs would mean less money and resources for the family to use. If food insecurity is not overcome, food insecurity becomes a barrier that prevents food-insecure ART patients from adhering to treatment optimally. Evidence suggests that actual experience or perceived food insecurity (i.e., fear of experiencing food insecurity at a later time) influences ART patients' decision to skip doses and only take medications when they have food (Young et al., 2014).

Further, food insecurity as a perceived barrier may affect PLHIV's perception of their competence to achieve and maintain optimal treatment adherence. If PLHIV do not have access to adequate food to take with their medications to optimize treatment outcomes, avoid acute hunger due to increased appetite, and prevent severe side effects, they may believe that they are not capable of adhering to treatment optimally. Because ART requires lifetime adherence, ART

adherence requires a good deal of confidence to initiate and maintain. Consistent with perceived barriers, people's perception of their efficacy to perform a particular health behavior has also been shown to be a strong predictor of engaging in that same behavior (Hounton, Carabin, & Henderson, 2005; Janz & Becker, 1984; Zak-Place & Stern, 2004).

Based on the HBM, ART patients will adhere to treatment if: 1) they believe that they are susceptible to adverse health outcomes due to their HIV positive status; 2) they believe that nonadherence has severe adverse health consequences (in this case worse immunologic and virologic outcomes that lead to more opportunistic illnesses and higher risk of mortality); 3) they believe that an available course of action (in this case optimal adherence) is effective in reducing either their susceptibility to adverse health outcomes or severity of health conditions; and 4) they believe that the anticipated barrier (in this case food insecurity) to performing the action is outweighed by the action's benefits (in this case longer, healthier and more productive lives due to optimal adherence to ART).

However, HBM has been criticized for being overly focused on individual decision-making and thus may have limited relevance when addressing HIV and food insecurity in non-western societies and resource-limited countries (Campbell, 2003; Tomlinson, Rohleder, Swartz, Drimie, & Kagee, 2010). Theoretical models that rely on rational choice ignore broader factors that operate outside an individual's ability to weigh costs and benefits but may have substantial influence on how food-insecure ART patients in SSA make adherence decisions. Unlike in resource-adequate settings where access to formal safety net mechanisms (e.g., Supplemental Nutrition Assistance Program and Special Supplemental Nutrition Program for Women, Infants, and Children in the United States) are established and cover most food-insecure households, lack of formal or institutionalized safety net arrangements in SSA constrains ART patients' ability to make decisions that maximize personal benefits (in this case ability to adhere to treatment). Broader economic and social issues are often more constraining on individual behaviors in many communities in SSA than in resource-adequate settings. For

instance, stigma and discrimination of PLHIV remains an important barrier to both food security and optimal treatment adherence in SSA (Dawson, 2013; Reda & Biadgilign, 2012; Tsai et al., 2011). Further, HBM and other intrapersonal models of health behavior may be difficult to test and therefore model propositions may be challenging to support or reject based on empirical investigations (Ogden, 2003). In the literature, few studies have examined ART adherence predictors that are explicitly based on the HBM constructs. Even fewer studies have applied the HBM constructs to support empirically the relationship between food insecurity and ART adherence. More research is needed to test the predictive powers of the HBM constructs (particularly perceived barriers and self-efficacy) in explaining why and how food-insecure ART patients are less likely to adhere to treatment optimally.

Social Cognitive Theory (SCT)

SCT highlights the importance of individual and environmental factors that influence health behaviors. SCT is a theoretical model of interpersonal health behavior that recognizes the influence of psychosocial dynamics on health behaviors. Within SCT, an individual's ability to perform a particular health behavior is explained through a triadic, dynamic, and reciprocal model in which the same health behavior, individual factors (including personal expectancies) and environmental influences (primarily from social relationships) are continuously interacting and reinforcing each other (Bandura, 1977; 1986). Personal expectancies can be outcome related (for example, beliefs about the consequences of optimal adherence to ART) or about individual competence (or personal efficacy to maintain optimal ART adherence). Based on SCT, beliefs about outcomes and beliefs of personal efficacy, or "beliefs in one's capabilities to organize and execute the courses of action required to produce given levels of attainment" (Bandura, 1998, p. 624), are major predictors of health behavior (Bandura, 1997; 1998).

According to SCT, PLHIV's beliefs about their personal efficacy to adhere to ART optimally within the context of food insecurity can be influenced by several sources. One of these sources is vicarious experiences (or learning by observation) through social models or

interpersonal relationships (Bandura, 1997; 1998). Witnessing other food-insecure ART patients adhere to treatment raises observers' beliefs that they too may possess the capabilities to succeed and attain optimal adherence. Alternatively, seeing other food-insecure PLHIV struggle to adhere to treatment diminishes observers' beliefs that they can also follow treatment as prescribed. For instance, seeing other food-insecure ART patients suffer from acute hunger due to increased appetite from taking ARVs and/or severe side effects exacerbated by the absence of food may influence other ART patients' decision to skip doses or only take medications when there is food in order to avoid adverse reactions. Empirical evidence supports the influence of observational learning on treatment adherence among food-insecure ART patients in SSA (Grant et al., 2008; Kalofonos, 2010; Weiser et al., 2010). In Mozambique, for instance, PLHIV who knew family or other community members who experienced severe hunger while on ART were discouraged to continue treatment because of fear that acute hunger may occur when ARV drugs are taken without food (Kalofonos, 2010).

In addition to observational learning, social persuasion influences people's beliefs about their personal self-efficacy (Bandura, 1998). In many communities in SSA, high rates of ART adherence in spite of economic obstacles such as food insecurity have been attributed to social persuasion, or the influence of important people's opinion on PLHIV's behavior or explicit expectations from PLHIV's essential relationships (for example treatment supporters, family members, friends, and health care providers) that they can adhere to treatment (Ware et al., 2009). Social persuasion may enable PLHIV to mobilize greater effort to succeed, fulfill social responsibilities, and preserve social relationships, which in turn, may ensure assistance will be available when future needs arise.

Learning by observation and social persuasion as sources of personal efficacy are relevant SCT constructs that may guide our understanding of the relationship between food insecurity and ART adherence. These two constructs are also important strategies that can be employed by ART patients to change their behaviors and maintain optimal treatment

adherence. SCT posits that if PLHIV believe they can overcome food insecurity, they are not worried that food insecurity will impede their ability to adhere to treatment. However, if they believe they cannot overcome food insecurity, they worry that the problem will impair their level of functioning (in this case optimal adherence to ART).

SCT shares similarities with HBM. Both theoretical models emphasize the importance of cognitive elements such as perceived self-efficacy as influential predictors of health behaviors. However, the significance of social relationships in enhancing personal efficacy distinguishes SCT from HBM. On the other hand, SCT, unlike HBM, does not explicitly include costs or barriers as predictors of behavior change. Consistent with other social cognition models, SCT has been criticized for focusing too much on individual decision-making and emphasis on rational choice, and thus may have limited relevance in resource-limited settings (Campbell, 2003). Although SCT recognizes the role of social relationships in health behavior change, SCT does not take into account that individual cognitions are shaped by larger contextual realities and structural issues that are beyond the immediate social networks of PLHIV (Kagee et al., 2011; Roura et al., 2009; Skovdal et al., 2011).

Conservation of Resources Theory (CoRT)

CoRT emphasizes the role of resources as predictors of health behaviors. CoRT posits that individuals accumulate resources that they can apply to accommodate, withstand, or overcome threats (Hobfoll, 1989). Resources can be personal, material or condition. Personal resources refer to personality traits such as self-esteem, self-efficacy and optimism. Material resources are tangible objects such as income, money and food. A resource can also be a condition such as status acquired from marriage, employment and other socioeconomic characteristics. Other resources that individuals accumulate include social support and physical energy. Some resources, such as reputation and social support, enable individuals to secure other resources. These types of resources are valued because they satisfy the survival needs of an

individual. CoRT hypothesizes that individuals thrive when they gain, maintain and conserve their resources (Hobfoll & Lilly, 1993).

Resources such as food and social support are critical for survival. These resources play an even greater role in ensuring that PLHIV achieve and sustain a higher quality of life. Adequate food and proper nutrition are critical to all stages of HIV infection. Food improves overall health and nutritional status, boosts immune system to fight opportunistic infections, optimizes treatment outcomes, and contributes to higher levels of ART adherence (de Pee & Semba, 2010; Drain et al., 2007; Weiser et al., 2011), among many other positive benefits. Further, social support is equally important to food security and optimal adherence of ART patients (Mills et al., 2006; Tsai et al., 2011). PLHIV and their households may derive food assistance from their social support networks. Social support networks may also be important sources of encouragement and motivations for PLHIV, which in turn, helps them to adhere to treatment optimally.

According to CoRT, when resources are limited or depleted, individuals' ability to address needs and demands becomes inadequate. For instance, lack of food or inability to access adequate food limits the ability of PLHIV to adhere to treatment optimally. Further, when individuals cannot satisfy needs or meet demands because of inadequate resources, they experience stress (Hobfoll, 1989). Higher levels of stress, in turn, influence a range of undesirable outcomes including various illnesses (Cohen & Williamson, 1991; Steptoe, 1991). For example, when PLHIV do not have adequate food, they may experience stress or anxiety that negatively affects their ability to adhere to treatment. Empirical evidence supports CoRT's hypothesis that food insecurity increases stress levels of PLHIV (Addo et al., 2011; Garcia et al., 2013). Higher stress levels or poor mental health status, in turn, predicts suboptimal adherence to ART (Kidia et al., 2015; Langebeek et al., 2014). In other words, being stressed about food insecurity affects the ability of PLHIV to take their medications as prescribed. Food-insecure PLHIV may experience stress because lack of food may lead them to believe that: a) treatment

may be less effective; b) severe side effects may occur when ARV drugs are taken without food; c) increased appetite due to ART would lead to acute hunger; and d) their limited (monetary) resources would have to be spent on food which means fewer resources to pay for ancillary treatment costs.

In addition to when resources are lost, the CoRT states that stress can occur when resources may be lost or are at risk of being lost. When resources are at risk of being lost, individuals experience anticipatory stress (Hobfoll, 1989). The effects of anticipatory stress can be as severe as actual stress (Hobfoll, 2001). Applying the concept of anticipatory stress to the relationship between food insecurity and ART adherence means that fear of food insecurity may lead to higher levels of stress among PLHIV. In turn, higher levels of stress negatively affect PLHIV's ability to adhere to treatment. Empirical evidence suggests that actual experience or fear of experiencing food insecurity contributes to suboptimal ART adherence (Young et al., 2014). In other words, being stressed about the possibility of not having enough food may negatively affect PLHIV's competence to take their medications as prescribed.

CoRT shares similarities with HBM and SCT. Consistent with HBM, CoRT recognizes the effects of resource loss on an individual's ability to perform a particular action (in this case ART adherence). The construct "perceived barriers" in the HBM is consistent with the idea of resource depletion in the CoRT. For PLHIV to successfully adhere to treatment, they need to obtain various resources (particularly food) in order to overcome perceived barriers (such as fear of food insecurity) to optimal ART adherence. Further, CoRT and SCT highlight the importance of interpersonal dynamics and social relationships in influencing individual outcomes. Both theoretical models agree that resources such as personal efficacy and social support are valuable because they satisfy the needs of PLHIV to survive (in this case the need to adhere to treatment optimally as an essential strategy to lower risk of mortality). However, unlike HBM and SCT, CoRT explicitly incorporates the concept of stress as a consequence of losing resources. Within the context of food insecurity and ART nonadherence, actual

experience of food insecurity or fear of food insecurity (whether it is transitory or chronic) is a stressful event that may considerably diminish the ability of PLHIV to maintain optimal ART adherence. In addition, by identifying that resources can be internal (such as personal) and external (such as material and condition), CoRT recognizes that environmental and individual factors are important determinants of health behaviors.

Memberships Theory of Poverty (MTP)

MTP emphasizes the role of group memberships in determining social, health, and economic outcomes. Unlike HBM, SCT, and CoRT which focus on individual-level explanations, MTP focuses on group-level explanations, including structural barriers, as predictors of individual outcomes (Durlauf, 2001). Although primarily developed as an economic model, MTP incorporates key concepts from sociology and social psychology. Unlike neoclassical economic models which put emphasis on individual characteristics and decisions as predictors of socioeconomic outcomes (Friedman, 1957; Modigliani & Ando, 1957), MTP assumes that individual outcomes are influenced by group memberships.

MTP posits that an individual's outcome, particularly the ability to engage in a particular behavior, depends on the composition of the various groups, over the life course, of which that same individual is a member (Durlauf, 1999, 2001). These groups can be exogenous (such as gender or ethnicity) or endogenous (such as education level or employment). Based on MTP, group memberships influence individual outcomes through different mechanisms such as peer group effects, role model effects, social learning, social complementarities, social network effects, and social norms (Durlauf, 2001). For instance, PLHIV with social networks that can provide tangible support (such as food assistance) are less likely to experience food insecurity and more likely to adhere to treatment optimally.

One salient group membership that may guide our understanding of the relationship between food insecurity and ART adherence is membership related to health conditions, more specifically being HIV positive. HIV infection heightens vulnerability to food insecurity by

limiting income and food production (Gillespie & Kadiyala, 2005; Weiser et al., 2011). Further, stigma and discrimination of PLHIV because of their chronic health condition may exacerbate food insecurity as PLHIV may find it more difficult to work and maintain a livelihood, access food, and support their families. In some cases, PLHIV may lack support from their families and other members of their social networks because of stigma and discrimination. In addition to being discriminated because of HIV, PLHIV who live in resource-poor communities with limited employment opportunities, poor health care access and quality, and absent social services are more likely to experience food insecurity than PLHIV who live in resource-rich communities with more economic opportunities and better services.

Because of the role of group memberships on health behavior change, HIV care and treatment providers in SSA have been employing a group-membership framework (i.e., a group defined by HIV status) to address more effectively the distinct causes and effects of food insecurity on PLHIV (Roopnaraine et al., 2012). The group-based model complements MTP's proposed mechanisms that influence behavior. For instance, participation in a group-based program enables participants to build social networks, observe and learn from other participants, and create social norms to be respected and enforced by group members. In turn, these mechanisms (for example, social networks, social norms, social learning, and role models) influence an individual's ability to perform a particular behavior (in this case optimal adherence to ART).

Consistent with SCT, MTP highlights the role of interpersonal dynamics and social relationships in predicting health behavior. Further, CoRT and MTP share similarities because both theoretical models recognize the function of tangible and intangible resources in facilitating behavior change. However, unlike individual-level models of behavior (such as HBM, SCT, and CoRT), MTP recognizes explicitly the influences of groups and structural barriers in predicting individual outcomes. Structural factors that characterize group memberships (such as being HIV positive and food insecure) may be particularly salient in resource-limited settings

where broader economic, social and political issues are often more constraining on individual behaviors. In sum, MTP broadens our understanding of the relationship between food insecurity and ART adherence.

Information-Motivation-Strategy Model (IMSM)

IMSM is a conceptual model that combines elements of HBM, SCT, CoRT, and MTP, while including a broader range of health behaviors, including treatment adherence. IMSM represents a model of behavior change. In contrast, HBM, SCT, CoRT, and MTP, in varying degrees, represent models of behavior or explaining health behaviors. In other words, IMSM informs program development by combining and operationalizing key propositions from HBM, SCT, CoRT and MTP into three separate but interrelated mechanisms that can be targeted and modified through an intervention. As illustrated in Figure 3, IMSM hypothesizes that before an individual can achieve health behavior change that individual must: 1) know what change is necessary (*information*); 2) have the desire to change (*motivation*); and 3) have the necessary tools, whether economic, financial or social, to achieve and maintain health behavior change (*strategy*; DiMatteo & Nicola, 1982; Martin, Haskard-Zolnierrek, & DiMatteo, 2010; Skovdal et al., 2011). In other words, IMSM postulates the constructs of information, motivation and strategy towards intervention development. In the case of food insecurity and treatment adherence, optimal ART adherence will be achieved when PLHIV: 1) know and believe that food is important to manage their HIV infection and maximize the benefits of ART; 2) are confident and competent to change and adhere to treatment; and 3) have tangible tools such as adequate food and financial resources to overcome barriers and carry out the health behavior change.

The flexible nature of IMSM allows it to incorporate evidence from empirical research, while remaining consistent with key constructs and assumptions of HBM, SCT, CoRT, and MTP. Consistent with IMSM, food and nutrition counseling provides PLHIV with *information* about the importance of adequate food and nutritious diet to optimize treatment outcomes, satisfy increased appetite, and avoid severe side-effects. Further, essential social relationships and their

influences (either through observational learning or social persuasion) on PLHIV's personal efficacy create *motivation* to adhere to ART. Social relationships may create powerful channels to encourage PLHIV to adhere to ART in spite of food insecurity. In addition, income from employment or other livelihood activities, or instrumental support in the form of food assistance from social networks provides tangible resources and *strategies* that are necessary to carry out a health behavior (i.e., PLHIV worry less about food and are more confident in their ability to adhere to ART). However, IMSM does not identify whether all three components (*information, motivation and strategy*) are equally important to ART adherence. Similarly, limited data are available to evaluate whether some factors are stronger predictors of adherence compared to others. Unlike other social-ecological models, IMSM does not specify any interrelationships of information, motivation, and strategy. For instance, ability to obtain information may be influenced by a person's motivation, which in turn, may be shaped by a person's access to tangible resources. Few studies have tested such propositions using empirical data of food-insecure ART patients in SSA. Thus, more research is needed to test IMSM, as an integrated theoretical model of health behavior change, with a sample of food-insecure ART patients in resource-limited settings.

Integrated Conceptual Framework for Food Insecurity and ART Adherence

Building on the key constructs and propositions outlined in the five theoretical models, I developed an integrated conceptual framework (see Figure 4) that: 1) attempts to explain the relationship between food insecurity and ART adherence; and 2) informs intervention development through synthesis and application of key theories into alterable mechanisms. Figure 3 presents this integrated framework. The integrated conceptual framework incorporates different levels of understanding the relationship between food insecurity and ART treatment adherence, and posits that cumulative factors at the individual, household, community, programmatic, and structural levels may explain how and why food insecurity contribute to suboptimal ART adherence. In addition, the conceptual framework features “entry points” at

distinctive levels that can be targeted by an intervention (in this case, an intervention to improve food security and ART adherence).

The integrated framework is distinct because of its specific application to describing various mechanisms in which food insecurity may contribute to ART nonadherence. In addition, the conceptual framework decodes the same theoretical propositions and various mechanisms into (three) malleable factors that can be manipulated by an intervention. First, the intrapersonal component (in Figure 4) is based on key HBM constructs (perceptions, beliefs and expectations). These constructs, in turn, form the information element of an intervention. The HBM and the information component of IMSM propose that PLHIV should have access to information that helps them to create perceptions about the importance of food and nutrition on their health and wellbeing, as well the as the significance of ART and adhering to therapy optimally.

Second, the interpersonal component (social relationship, learning by observations, social persuasion) is adapted from SCT and MTP. These theoretical propositions substantiate the motivation element of an intervention. SCT, MTP, and the motivation component of IMSM postulate that social relationships and their effects on individual cognitions and group dynamics strongly influence health behaviors within the context of food insecurity. Lastly, the third component pertains to environmental factors that predict access to food and its effect on ART adherence. These environmental factors (e.g., group membership, tangible and intangible resources, and level of stress) are consistent with CoRT and MTP. These factors build the strategy component of an intervention. CoRT, MTP, and the strategy element of IMSM recognize the importance of resources (that are beyond an individual's control), as well as their effects on psychosocial functioning, in predicting access to food and maintaining positive health behavior change.

Summary

A single level of understanding health behavior may not adequately explain the relationship between ART adherence and food insecurity in SSA. A constellation of cognitive, psychosocial, material, and structural factors may more convincingly explain why food-insecure PLHIV are less likely to adhere to ART optimally, compared with their food-secure counterparts. An integrated conceptual framework that takes into account the influence of personal, social and environmental factors on cognition and behavior, with particular attention to mechanisms in which treatment adherence is enabled or limited by a larger structural background – that in many parts of SSA includes poverty and food insecurity – may be more relevant in understanding why food insecurity acts as a barrier to treatment adherence. A broader perspective on understanding food insecurity and ART adherence beyond an “individualistic” or “structuralist” perspective only may be required if substantial contributions to the betterment of food-insecure PLHIV is to be achieved. A more holistic theoretical framework that incorporates intrapersonal, interpersonal, and environmental factors may also help identify feasible and appropriate “entry points” for multilevel interventions that promote food security as a way to improve ART adherence.

Program Model: Integrated HIV and Livelihood Program

An integrated HIV and livelihood program is one promising approach to increase food insecurity and improve ART adherence. The program model for an IHLP can be traced using the integrated conceptual framework of food insecurity and ART adherence (explained in section 1 of this chapter). The program framework, an example is illustrated in Figure 5, incorporates economic, health and social constructs that are hypothesized to be improved or affected by an IHLP. The economic, health and social constructs are shaped by individual, interpersonal and environmental factors that are consistent with the theoretical models outlined in the integrated conceptual framework.

The program model for an IHLP differs from the integrated conceptual framework in two important ways. First, the program model does not attempt to explain the problem. Instead, the program model describes how an intervention attempts to change or improve outcomes by incorporating and manipulating mechanisms that explain the relationship between food insecurity and ART adherence. Second, the program model – using the integrated conceptual framework – identifies the variables that are hypothesized to be improved by an IHLP, including direct and indirect effects. For instance, an IHLP generally includes information or knowledge-building components. Information components may vary but typically include health education. Health education focuses on relevant topics such as importance of food and nutrition, as well as benefits of ART adherence. In other words, IHLP provides the necessary information about food and ART that may help participants assess the benefits and barriers to treatment adherence, as well as their personal efficacy to adhere to treatment despite barriers such as inadequate access to food.

Further, in an IHLP, social relationships are based primarily on the concept of group membership, in particular as people living with HIV. Recognizing that being HIV positive presents unique strengths and challenges, IHLP, through group-based training, creates opportunities for social learning with other PLHIV who understand the day-to-day experiences of being food insecure and on ART. IHLP offers several opportunities for group-based learning and interaction among participants. For instance, sessions on business management, financial literacy, food and nutrition, and HIV treatment are delivered typically using classroom-based techniques that allow peer-to-peer interaction and learning. Also, IHLP participants sometimes create self-help groups that function as a support group to ensure optimal treatment adherence and/or to assist in implementing livelihood activities. Through contact with other PLHIV, IHLP participants can learn through observations, role modeling, and/or social persuasions how to cope with food insecurity while at the same time adhering to ART optimally. Outside their family members and relatives, an IHLP may also expand PLHIV's social support network to include

other PLHIV, health care providers, and livelihood expert who are trained to be respectful and sensitive to PLHIV's situation. In other words, being part of a group that empathizes or shares similar experiences may motivate PLHIV to perform desirable health behaviors or to change their current detrimental behaviors to something beneficial.

Because of its multifaceted nature, an IHLP may allow participants to accumulate different types of resources. These resources can be personal (such as optimism and self-efficacy) or interpersonal (such as social support). More importantly, resources that can be obtained from an IHLP include material or tangible objects such as income and food. IHLP's focus on livelihood and development of income-generating activities offer PLHIV concrete strategies to earn income and have money to buy food, or the ability to produce food for household consumption and income generation. These resources, in turn, become the strategies or necessary tools to achieve and maintain health behavior change. For instance, with material resources such as adequate food, PLHIV may be more likely to take their medications as prescribed because they do not have to fear that taking ARV drugs without food would result in severe side effects, acute hunger, and/or poor treatment efficacy. Also, higher income from IHLP means more resources to satisfy treatment-related costs and meet other household non-treatment-related expenses. In sum, these material resources, together with personal and social assets, may make it less stressful on the part of PLHIV to adhere to ART optimally and sustain optimal adherence for a longer period of time.

Empirical Support for the Program Model

Empirical evidence supports the proposed relationships outlined in Figure 5. For instance, the model's mediators and covariates are known facilitators or barriers to ART adherence in SSA (Mills et al., 2006; Langebeek et al., 2014; Lankowski et al., 2014; Posse et al., 2008; Reda & Biadgilign, 2012; Sasaki et al., 2012; Weiser et al., 2014). Financial constraints, including income insufficiency, are negatively associated with optimal ART adherence of PLHIV in SSA and other resource-limited settings (Bezabhe et al., 2014; Byakika-Tusiime et al., 2005;

Gusdal et al., 2009; Sanjobo et al., 2008; Weiser et al., 2003). Also, food insecurity is emerging as a major barrier to optimal treatment adherence among ART patients in SSA and other resource-limited settings (Singer et al., 2015; Young et al., 2014). Similarly, food security improves ART adherence (Audain et al., 2015; de Pee et al., 2014; Tirivayi et al., 2012). At the most basic level, higher and regular incomes make it easier to put food on the table every day. Poor mental status such as higher level of stress, feeling of hopelessness, lower personal efficacy, and inability to think of the future in a positive way predicts lower ART adherence rates among PLHIV in SSA (Kidia et al., 2015; Langebeek et al., 2014; Mills et al., 2006). Food insecurity is also associated with higher levels of mental distress among PLHIV in SSA (Addo et al., 2011; Palermo et al., 2013; Tsai et al., 2012).

In addition to correlational studies, several examples of intervention research support the program model. These intervention studies include experimental and quasi experimental studies of food assistance programs for PLHIV (Aberman et al., 2014; Audain et al., 2015; Palar et al., 2015; Tirivayi & Groot, 2011), and experimental and quasi-experimental studies of multifaceted livelihood programs for PLHIV and non-PLHIV (Aberman et al., 2014; Banerjee et al., 2015; Dunbar et al., 2014; Hardee et al., 2014; Ssewamala & Ismayilova, 2009). For instance, two food assistance programs in Zambia found that adherence to ART was higher among PLHIV who received food supplementation compared with their peers who did not receive food aid (Tirivayi et al., 2012) or were scheduled to receive food aid at a later time (Cantrell et al., 2008). Similarly, food assistance programs in SSA improved food security of PLHIV and their households (de Pee et al., 2014; Rawat et al., 2014). Quasi-experimental livelihood programs for PLHIV have also contributed to higher household income and food security (Pandit et al., 2010; Wagner, Rana et al., 2012). In addition, livelihood interventions for the general population have found positive effects on economic and health outcomes (Chowa, Masa, & Sherraden, 2012; Boccia et al., 2011; Dunbar et al., 2014; Ssewamala, Han, & Nielands, 2009; Ssewamala, Neilands, Waldfogel, & Ismayilova, 2012). For instance, a randomized multifaceted livelihood

program implemented in six resource-poor countries including Ethiopia and Ghana had long-term positive impacts on household income, food security and mental health status including lack of stress (Banerjee et al., 2015). In rural Rwanda, an integrated food security and livelihood program for people living in extreme poverty resulted in significant improvements in access to food and actual food consumption (Nsabuwera et al., 2015). Furthermore, livelihood programs targeted to populations that are at high risk of HIV infection or living with other chronic health conditions have contributed to better health outcomes including frequent engagement in HIV-protective behaviors (Dunbar et al., 2014; Kennedy et al., 2014; Pronyk et al., 2008; Witte et al., 2015) and successful (non-HIV) treatment completion (Ahmed, Petzold, Kabir, & Tomson, 2006; Rocha et al., 2011).

Despite evidence from correlational and intervention studies that support the hypothesized relationships in the program model, important gaps in knowledge and research remain. In particular, few studies have evaluated the effects of integrated HIV and livelihood programs on HIV-treatment related outcomes including ART adherence. This gap in knowledge exists because: 1) few livelihood programs have specifically targeted PLHIV including those receiving ART; 2) the growing number of IHLPs in SSA and elsewhere has not been rigorously designed and studied; and 3) the few IHLPs that have been systematically examined did not have ART adherence (or other HIV-treatment related outcomes) as an outcome.

Definition of Concepts and Research Questions

Definition of Key Concepts in the Program Model

Integrated HIV and livelihood program. IHLPs are interventions that combine HIV treatment with household economic strengthening activities. By definition, IHLPs are multifaceted. As explained in Chapter 1, IHLPs are designed to address economic and social barriers to better HIV treatment outcomes (including ART adherence) by providing PLHIV with a livelihood. A livelihood is defined as set of capabilities, assets and activities that are required for means of living (Chambers & Conway, 1991). Livelihood is a broad term that covers various

strategies (for example, social and economic, and individual and household) to secure income. Consistent with the definition of livelihood, livelihood interventions that have been integrated with HIV treatment programs cover a broad set of household economic strengthening activities (Aberman et al., 2014; Kennedy et al., 2014). These activities include direct transfer of cash or assets, technical skills training related to a specific income-generating activity, life or soft skills training such as financial literacy, and/or access to financial services such as savings products and credit services.

Although PLHIV may receive treatment other than ART (for example, prophylaxis for opportunistic infections or medications to prevent side-effects), HIV treatment is defined primarily as receipt of antiretroviral therapy. When to start ART in people living with HIV varies depending on age (adults and adolescents versus children) and condition (for example, pregnant and breastfeeding women) of the patient. The WHO (2013) outlines three recommendations when to start ART in adults living with HIV. First, ART should be initiated in all adults living with HIV with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤ 350 cells/mm³. Second, ART should be initiated in all adults living with HIV with CD4 count > 350 cells/mm³ and ≤ 500 cells/mm³ regardless of WHO clinical stage. Third, ART should be initiated in all adults living with HIV regardless of WHO clinical stage or CD4 cell count in the following situations: a) adults with HIV and active tuberculosis; b) adults coinfecting with HIV and Hepatitis B with evidence of severe chronic liver disease; and c) partners with HIV in serodiscordant couples to reduce HIV transmission to uninfected partners.

Food security. As described in Chapter 1 (in greater details), food insecurity is a multidimensional construct generally conceptualized in three dimensions: availability, access, and utilization (FAO, 1996; Woller et al., 2011). In this dissertation, food insecurity is primarily defined as access to food. In other words, food insecurity refers to inadequate access to food due to lack of resources that are used to produce or purchase food. Although resources can be both tangible and nontangible, economic and social, resources, as defined in this dissertation, refers

to tangible economic resources such as cash (from income or savings) and in-kind transfers. This dissertation focuses on access because access is closely associated with social and economic status of an individual or household (Barrett, 2010; Sen, 1981). In particular, the ability to access food is affected by how many tangible economic resources an individual or household possesses. Further, in this dissertation, access to food is classified based on level of severity – food secure, mildly food insecure, moderately food insecure, and severely food insecurity. As explained in Chapter 1, these categories of food insecurity describe the various coping strategies and the frequency of using such strategies to deal with inadequate access to food. Definitions of the categories of food insecurity based on severity level are described in Chapters 1 and 4.

Adherence. As described in Chapter 1, adherence is defined broadly as the extent to which an individual's behavior corresponds with recommendations from a health care provider (Sabaté, 2003). Consistent with the concept of food insecurity, adherence is a multidimensional construct that covers various types of health behaviors including taking medication appropriately (or medication adherence). Within medication adherence, adherence may pertain to amount of medication (dose), timing of taking prescribed drugs (schedule/interval), or frequency (for example, once-a-day or twice-a-day). In the adherence literature, ART adherence has been commonly described as dose adherence. Consistent with the literature, ART adherence is defined in this dissertation as dose adherence, or the amount of medications taken by a patient relative to the amount of medications prescribed. Further, *optimal* dose adherence is primarily defined as $\geq 95\%$ of prescribed ARV medications taken. This definition of optimal adherence is consistent with the literature on ART adherence (Alexander et al., 2003; Pasternak et al., 2012; Paterson et al., 2000; Wood et al., 2006).

Antiretroviral therapy. Antiretroviral therapy refers to the use of a combination of three or more ARV drugs or medications that treat HIV. In the literature, ART is synonymous with the terms “combination ART” and “highly active ART.” The goals of ART include long-term

viral suppression, restoration and/or preservation of immunologic function, prevention of HIV transmission, and reduction of HIV-related illness and death.

The choice of ARV drugs to include in an ART regimen depends on a person's individual needs. As a general rule, PLHIV and their health care providers may consider the following factors when selecting a treatment regimen: presence of comorbid conditions, possible side effects of ARV drugs, potential interactions between ARV drugs or between ARV drugs and other medicines, signs of drug resistance, costs, virologic efficacy, toxicity, and convenience of the regimen (such as pill burden and dosing frequency). ART patients begin their treatment with the WHO (2013) current standard initial treatment options (or first-line regimen). ART regimen may be changed due to various reasons such as treatment failure, toxicity, and intolerance or prolonged side effects. ART patients who do not respond well to initial therapy (or first-line regimen) are switched to a second-line therapy. Appendix C describes the different ARV drugs and the WHO treatment guidelines.

Research Questions

Guided by the integrated conceptual framework and program model for IHLP, this dissertation aims to address four main research questions using data from a pilot study in Zambia:

- 1) What is the prevalence of food insecurity in a sample of ART patients in Eastern Province, Zambia? (labeled R1 in Figure 5)
- 2) What are the risk factors associated with food insecurity among PLHIV in rural Eastern Province, Zambia? (labeled R2 in Figure 5)
- 3) What is the relationship between food insecurity and ART adherence among PLHIV in rural Eastern Province, Zambia? (labeled R3 in Figure 5)
- 4) What is the impact of participation in an IHLP on food security and ART adherence? (labeled R4a and R4b in Figure 5)

Research question 1 examines the prevalence of food insecurity, including the degree of food insecurity (whether it is mild, moderate or severe). Although prior studies have investigated the prevalence of food insecurity among ART patients in Zambia (for example, Cantrell et al., 2008; Tirivayi et al., 2012), most studies have focused on ART patients in urban areas particularly Lusaka. Little is known about the extent of food insecurity among PLHIV in rural areas of the country, including the eastern part of the country.¹⁰ Similarly, little is known whether prevalence of food insecurity among PLHIV is higher in rural versus urban areas, or vice-versa. In the general population, prior studies have shown mixed results when it comes to food insecurity levels in rural versus urban areas. Some studies have shown that food insecurity tends to be higher in urban versus rural households (Walsh & van Rooyen, 2015), whereas other studies have found the opposite pattern, with more food-insecure households in rural versus urban areas (Usfar, Fahmida, & Februhartanty, 2007). In sum, question 1 addresses gaps in knowledge when it comes to prevalence of food insecurity among PLHIV in rural communities in SSA.

Research question 2 identifies the predictors of food insecurity among PLHIV in rural communities in Zambia. Consistent with limited evidence on prevalence of food insecurity in rural Zambia, little is known about the risk factors that are associated with higher risk of food insecurity among PLHIV on ART. Similarly, limited empirical evidence exists on protective factors that lower the risk of food insecurity among PLHIV on ART. Although numerous studies have investigated facilitators and barriers to ART adherence among PLHIV that attend rural or urban health facilities in Zambia (e.g., Birbeck et al., 2011; Carlucci et al., 2008; Grant et al., 2008; Jones et al., 2014; Murray et al., 2009; Sasaki et al., 2012), few studies have explored factors that predict food security/insecurity among ART patients in Zambia. Prior studies on

¹⁰ Although there have been research studies done in Lundazi District, Eastern Province, I am not aware of published studies that focus on food insecurity and/or ART adherence. Prior studies on ART adherence and/or food insecurity among PLHIV in Zambia have been conducted in Lusaka, Southern Province, Central Province, and Copperbelt Province.

determinants of food insecurity among PLHIV in SSA (e.g., McCoy et al., 2014; Nagata et al., 2012; Tsai et al., 2011) will guide inclusion of variables in the models. These variables include demographic (e.g., age, gender, marital status, occupation), economic (e.g., household size, income, asset ownership, living conditions), and health (e.g., self-perceived health, perceived stress) characteristics. Given the significance of access to adequate food on health and wellbeing of ART patients, question 2 will begin identifying potential alterable factors that can be the focus of food security interventions for PLHIV in rural Zambia and similar communities in the region.

Research question 3 investigates the relationship between food insecurity and ART adherence among PLHIV in rural Zambia. This research question builds on existing body of evidence on the relationship between food insecurity and ART adherence in SSA. Consistent with conceptual and theoretical evidence (Musumari et al., 2014; Singer et al., 2015; Weiser et al., 2014; Young et al., 2014), I hypothesize that food insecurity negatively predicts optimal adherence to ART. In other words, food-insecure ART patients are less likely to adhere to therapy optimally compared with food-secure ART patients. Question 3 also examines the relationship between food insecurity and ART adherence based on degree of food insecurity, consistent with previous studies in SSA (e.g., Hong et al., 2014; Musumari et al., 2014).

Although prior studies have examined the relationship between food insecurity and ART adherence among PLHIV in Zambia, these studies are either qualitative or conducted in urban communities (e.g., Murray et al., 2009; Sanjoko et al., 2008). In sum, question 3 addresses research gaps, including quality of empirical evidence, on the relationship between food insecurity and ART adherence among PLHIV in Zambia particularly in rural communities.

Research question 4 examines the direct impact of *Health & Wealth*, a pilot IHLP intervention, on food security and ART adherence. This research question aims to address critical gaps in knowledge and practice in the areas of livelihood and HIV treatment. This research question also aims to provide evidence of potential causal relationships between IHLP participation, and ART adherence and food security. Although food assistance programs in

Zambia have been shown to have positive effects on ART adherence (Cantrell et al., 2008; Tirivayi et al., 2012), no published IHLP studies in Zambia have been systematically evaluated to determine impacts on food security and ART adherence. Similarly, in SSA, few IHLPs have been systematically studied to investigate causal effects on these two types of outcomes. Findings from this dissertation, to the best of my knowledge, will be one of the first studies to provide rigorous evidence on the impact of IHLPs on food security and ART adherence of PLHIV in a resource-limited setting.

CHAPTER 3: RESEARCH DESIGN AND METHODS

Health & Wealth was a pilot integrated HIV treatment and livelihood intervention that was designed to test its feasibility and effects on economic, social and health outcomes for PLHIV who are receiving antiretroviral therapy. Although *Health & Wealth* aimed to address cumulative risk factors that contribute to adverse outcomes among ART patients in Zambia and test impacts on a broad range of outcomes, this dissertation focused on two key aspects of the project as it relates to food security and ART adherence. *Health & Wealth* was implemented in Lundazi District, Eastern Province, Zambia. Background information on Zambia is described in Chapter 1. Figure 2 shows the location of Eastern Province and Lundazi District.

Project Setting

Eastern Province. Eastern Province is one of Zambia's ten provinces. The province borders Malawi to the east, Mozambique to the south, Central and Muchinga provinces to the north, and Central and Lusaka provinces to the west. Eastern Province is the seventh largest province in terms of land area, covering 51,476 square kilometers. Comparatively, Eastern Province is larger than Maryland but smaller than West Virginia. Eastern Province consists of nine districts – Chadiza, Chipata, Katete, Lundazi, Mambwe, Nyimba, Petauke, Sinda and Vubwi. As of 2010, Eastern Province had a population of 1,593,000, or 12% of Zambia's total population. The Province has a population density of 30.9 persons per square kilometer (CSO, 2012a). Eastern Province is the third most populous province, after Lusaka and Copperbelt. The provincial capital is Chipata.

Eastern Province is predominantly rural, with 87% of the population living in rural areas (CSO et al., 2015). Consistent with the national pattern, 51% of the population is female. In 2010, Eastern Province had 342,000 households, with an average household size of 5.2. Twenty-

three percent of households were female-headed households. In terms of employment status, 93% were employed in the informal sector, i.e., they were not entitled to paid leave and pension or social security, and worked in an establishment with five or fewer employees. Women (97%) were more likely to be engaged in informal employment than men (90%). In 2010, 90% of workers in informal employment worked in agriculture (CSO, 2012b).

Given Eastern Province's predominantly rural landscape, most households are engaged in crop growing, and/or livestock and poultry-raising. In 2010, 91% of all households were agricultural – 96% of rural households and 49% of urban households. The proportion of urban agricultural households in Eastern Province is the highest in the country. Maize and cassava are the most commonly produced crop in the province, with 97% and 88% of households reported growing these crops in 2008/2009 season. Consequently, Eastern Province produced the most maize in all of Zambia – at 456 metric tons. In terms of livestock ownership, 23% of all cattle, 15% of all goats, and 58% of pigs in the country were raised in Eastern Province (CSO, 2012b). However, compared with other parts of the country, the eastern parts of Zambia tend to have the least rainfall (ranging from 600 mm to 1,100 mm annually), which increases risk of drought and affects local agricultural and food production (CSO et al., 2015).

Poverty remains pervasive in the province. An estimated 78% of the population is living in poverty, which is the third highest in the country. Further, 59% of the population is estimated to be living in extreme poverty, which is also the third highest in Zambia. In terms of household economic status, average monthly household income in the province was estimated at 607,000 ZMK (or approximately 117 USD) in 2010. Average income in Eastern Province tends to be lower than the national average. Real monthly per capita income in 2010 was 144,000 ZMK, the second lowest in the country. Although the average household monthly expenditure is lower than the national average, households in Eastern Province spend a significant portion of their income on food. In 2010, 63% of monthly household expenditures were spent on food items – one of the highest in the country. The percentage of household expenditure on food also

increased in the Eastern Province, from 53% in 2006 to 63% in 2010. (CSO, 2012b). Further, wealth inequality remains a critical economic issue in Eastern Province. Nearly 60% of the population belongs to the two lowest wealth quintiles compared with 4.2% of the population in the highest quintile (CSO et al., 2015). This pattern is consistent with the country-level trend, i.e., rural households are mostly distributed in the lowest, second, and middle wealth quintiles.

Finally, HIV remains an urgent social and public health issue in Eastern Province. HIV prevalence in Eastern Province was estimated at 10.3% in 2007, nearly 3.5 percentage points lower than in 2001 (13.7%). A slightly higher percentage of women (11% to 12%) are living with HIV compared with men (8% to 9%; NAC, 2014a). In the most recent Demographic and Health survey, 63% of men and 55% of women aged 15 to 49 in Eastern Province were perceived to be at risk of HIV infection (CSO et al., 2015). Further, 15% of adults were considered to be at high risk of HIV infection. In Eastern Province, access to HIV treatment and care are provided mainly at level-1 or district hospitals.

Lundazi District. Lundazi District is the northernmost district in Eastern Province, and comprised of three constituencies – Chasefu, Lundazi and Lumezi. Based on the 2010 Zambian Census, Lundazi District had a population of 314,281, the third largest in Eastern Province (CSO, 2011). Approximately 51% (or 161,588) of the population were women. The district had a population density of 22.4 people per square kilometer, with a total land area of 14,058 square kilometer. The district's main ethnic groups are Tumbuka and Chewa; whereas Tumbuka is the district's most widely spoken language. Consistent with patterns at the provincial level, Lundazi District is predominantly rural with more than 90% of the population living in rural areas (CSO, 2012a). Agriculture is the most common occupation for men and women. Lundazi District is one of the highest producers of maize, cotton, groundnuts, and tobacco in the country. Most of the district's annual agricultural output is produced by an estimated 68,000 small-scale farmers (Zimba, 2015).

Lundazi District was selected as the site of the pilot project because it is a rural, low-income district with high prevalence of HIV. Lundazi District has an estimated HIV prevalence rate of 15%, the second highest in Eastern Province after Chipata District. HIV prevalence rate in Lundazi District is higher than the prevalence rates in Eastern Province (10.3%) and Zambia (12.5%). Fifty-six percent of PLHIV in Lundazi District are women (NAC, 2014a). Within Lundazi District, two health facilities were selected as project sites. The two health facilities were located in Lundazi and Lumezi. The distance between Lundazi and Lumezi is 33 kilometers.

Lundazi. Lundazi is the center or “county seat” of Lundazi District. Based on the 2010 Census, Lundazi had a population of 130,325 living in 24,975 households. Fifty-one percent (or 66,743) of the population were female (CSO, 2012a). Lundazi’s local economy is dominated by agriculture and trading. Lundazi is 184 kilometers from Chipata, the capital of Eastern Province.

Lumezi. Lumezi is one of three constituencies in Lundazi District. Based on the 2010 Census, Lumezi had a population of 93,717 living in 17,805 households. Fifty-one percent (or 47,730) of the population were female (CSO, 2012a). Lumezi is 151 kilometers from Chipata. In recent years, Lumezi is fast becoming a trading center, with numerous small-scale mining operations (V. Nyirenda, personal communication, June 19, 2015).

Project Description

Consistent with multifaceted economic strengthening programs for the general population, *Health & Wealth* (treatment) participants ($n = 50$) received: 1) cash transfer (valued at 200 USD) to purchase an income-generating asset; 2) small business management training; 3) access to savings account and financial education; and 4) health training tailored to the needs of ART patients, in addition to medication adherence counseling. Control group participants ($n = 51$) received medication adherence counseling only.

Project innovation. *Health & Wealth* aimed to evaluate the efficacy of a household economic strengthening program as a potential health intervention. Although interventions to promote long-term ART adherence have been developed and tested in SSA (Bärnighausen et al.,

2011; Chaiyachati et al., 2014; Mills et al., 2014), few interventions have directly addressed economic barriers (for example, food insecurity) to medication adherence in resource-limited settings. Many adherence interventions, such as treatment or peer supporters, diary cards, directly observed therapy, and mobile phone short message services, tend to focus on modifying patient-level predictors to foster optimal ART adherence. In recent years, a number of programs have directly tackled lack of food as a barrier to ART adherence. Most of these programs provide short-term food assistance (Audain et al., 2015; Tirivayi & Groot, 2011). Unlike food assistance programs for PLHIV but consistent with IHLPs, *Health & Wealth* promotes a more sustainable approach to generate income and improve food security. Although food supplementation programs have positive effects on ART adherence (Audain et al., 2015; de Pee et al., 2014), these programs may be limited by its lack of sustainability – both in terms of access to food and positive impacts. An extensive comparison of different food security programs for PLHIV, including the advantages of IHLPs, is presented in Chapter 1 and Appendix B.

Intervention delivery. The training intervention was offered in a participatory workshop based on adult learning principles. All topics were taught based on training manuals on business management, managing money, financial education, and health and nutrition for PLHIV. Although most of the manuals were in English, training agents were fluent in Tumbuka (a common local language spoken in Lundazi District), which made facilitation easier and learning more relevant to participants. Also, because the program was for PLHIV, facilitators were trained to avoid using stigmatizing language, and instead use language that was sensitive to PLHIV. Consistent with the training manuals, facilitation methods and teaching aids included interactive group-based activities (e.g., role play, song composition, small-group discussion) that promoted and encouraged peer-to-peer learning. Each learning session followed the general pattern of: 1) introduction of topics and objectives; 2) explanation of topics; 3) use of real-world examples to illustrate topics; 4) exercises to encourage interactive and dynamic learning; and 5) wrap-up and restatement of key objectives. Financial literacy, business management, and

nutrition training were conducted in the second week of June 2015. The training took place for five consecutive days. Patients received medication adherence counseling before the intervention training. Finally, Seba savings accounts were opened after the training, and cash grants were directly deposited into participants' accounts in two installments of K700 and K500.

Cash transfer. For treatment group participants, the cash transfer to purchase an asset(s) was intended to help participants generate additional income through the operation of a microenterprise. Unlike previous IHLPS (e.g., Pandit et al., 2010; Wagner, Rana et al., 2012) that provided microloans or microcredit to PLHIV, the cash and assets were given as a grant. No payment for these assets was expected of participants. The “cash transfer” component was akin to cash transfer programs in many African countries. However, unlike the regular cash transfer programs, participants were not required to satisfy human development conditions. The cash transfer was directly deposited into the savings account of each participant.

During the small business management and financial education training, treatment participants expressed their goals for the cash transfer. Most participants planned to use their cash grants to start a retail business, including buy and sell of livestock or other types of goods (Victor Nyirenda, personal communication, June 12, 2015). For instance, a few participants mentioned buying goats at an order price of K100 per goat, and selling the goats at K250 at Lumezi market. Some participants planned to raise (broiler) chickens and sell chicken meat at Lumezi boarding school. In addition to livestock, participants proposed to buy raw materials that would allow them to make products (e.g., bags) that they can sell at Lumezi trading center. Some participants also wanted to start a business that buys mobile phones from vendors near the border with Malawi and then they sell the phones at trading markets in Lumezi. Although participants intended to use the cash transfer for various purposes, an overall theme was that the cash transfer was expected to provide financial capital necessary to start participants' livelihood or income-generating activities.

Skills training. In addition to cash transfer for an income-generating activity, participants received two types of economic-focused training, small business management and financial education. Both components were designed to enhance participants' knowledge and skills to manage their income-generating activities and improve profitability, while recognizing household needs such as food. Small business management training covered the following topics: record keeping, separating business and personal money, sales and profits, losses, and using profits to meet business and personal needs. Financial education included the following topics: learning about money, planning for the future, importance of saving and various saving methods, and formal banking which covered key banking activities (e.g., deposits and withdrawals) and financial products and services (e.g., savings account, ATM, account book balance and customer service inquiries).

Access to savings account. Because imparting knowledge alone may not be enough to facilitate and maintain (economic) behavior change, a savings account was opened for treatment participants. Consistent with theoretical propositions (Beverly & Sherraden, 1999; Beverly et al., 2008) and empirical evidence (Chowa, Masa, & Ansong, 2012; Dupas & Robinson, 2013; Kiiza & Pederson, 2001), low-income PLHIV and their households are unable to save primarily because they may not have the same institutional opportunities (i.e., access, information, incentives, facilitation, expectations, restrictions, and security; Beverly et al., 2008) as their wealthier counterparts. The savings account component provided treatment participants with two of these institutional opportunities – access and security. Savings account was meant to: a) extend access to financial products and services to poor PLHIV, many of whom were out of reach of formal financial institutions; b) provide unbanked PLHIV with a secure way to set aside money for future use; and c) promote positive saving behaviors and shape worldviews about the future.

The savings accounts were offered by Zambia National Commercial Bank (ZANACO). ZANACO is one of Zambia's largest commercial banks and licensed by the Bank of Zambia.

ZANACO has banking presence in 10 provinces and 74 districts of Zambia, including a full-service branch in Lundazi. The savings account opened for treatment participants was the Seba account, which is a low-cost savings account for small-scale entrepreneurs or lower income individuals. The Seba account is an interest bearing account with a required minimum balance of K50 (or approximately 7 USD). The minimum balance to be kept in the account was deducted from the overall amount of the cash grant. The account includes a free debit card, internet and mobile phone banking, and free monthly statements. The account has a monthly maintenance fee of K10 and a below minimum balance of K10 per occurrence. ZANACO customers can deposit and withdraw money at any ZANACO Xpress banking agent located all over the country, including Lundazi District.

Health education. Given *Health & Wealth* targeted PLHIV to increase their adherence to ART, a health component tailored to the needs of ART patients was added. The health training covered the following topics: good food and proper nutrition, increasing appetite, nutrition assessment, impact of ART on nutrition, improving diet to enhance nutrient absorption and drug efficacy, managing ARV side effects, and proper sanitation (including handwashing, water safety and personal hygiene).

Medication adherence counseling. All participants received medication adherence counseling. This type of counseling is offered to all PLHIV who are enrolled in HIV treatment programs. The objective of medication adherence counseling is to encourage and support ART patients in taking their ARV drugs as prescribed. ART peer educators (or “adherence counselors”) provide adherence counseling. Peer educators were trained to explain appropriately various topics related to HIV medication adherence based on a standardized ART care manual approved by the Ministry of Health. Topics included positive benefits of ART, management of drug side-effects, importance of regular clinic visits, strategies to integrate pill-taking into daily routines, and sexual risk reduction. Generally, ART patients receive adherence counseling at the beginning of treatment. However, they may also obtain counseling during

follow-up clinic and/or pharmacy visits. ART patients may receive counseling either through patients' voluntary action or referral from health workers.

Sample

The project's sample included two health facilities in Lundazi District and 101 PLHIV who were receiving antiretroviral therapy at the two selected health facilities. The health facility in Lundazi was the Lundazi District Hospital (LDH); and the health facility in Lumezi was the Lumezi Mission Hospital (LMH). The two health facilities were the most comparable of all health facilities in Lundazi District. At each health facility, ART patients were randomly selected from the pool of eligible participants and offered the opportunity to participate in the study. Fifty ART patients were recruited at LMH, and 51 ART patients were recruited at LDH, for a total study sample size of 101. All participants provided written informed consent.

Inclusion criteria. The study's inclusion criteria were the following: a) at least 18 years old but not older than 50 years old; b) economically poor; c) HIV positive and receive outpatient medical care including ART at either LDH or LMH; d) not pregnant; and e) not severely underweight or clinically unstable. Economically poor refers to individuals who are living below the Zambia national poverty threshold. The national poverty line is estimated at 435,000 Zambian kwachas per month (or approximately 90 USD; CSO, 2012a). Because the pilot project aimed to evaluate effects of income-generating activities, the study prioritized inclusion of PLHIV who were more likely to participate fully and be interested in a livelihood such as a microenterprise. Persons younger than 18 years old may still be economically dependent on their parents or guardian and/or attending school, and they are less likely to have or need a microenterprise for their income. Persons older than 50 years old are less economically active in Zambia and less likely to benefit from an intervention aimed at increasing income-generating activities. Severely underweight (i.e., BMI < 16.00 kg/m), clinically unstable patients (e.g., displaying symptoms consistent with WHO clinical stage 4 classification), and

pregnant women were excluded because their conditions may limit their ability to participate fully in all intervention activities.

Recruitment. At each health facility, the ART enrollment list was used to select and recruit participants. From the initial ART enrollment list, I created a list of eligible participants based on the inclusion criteria. From the list of eligible participants, I randomly selected 75 to 100 ART patients. The list of eligible ART patients was given to the project manager to recruit study participants. Recruitment continued until 50 ART patients per health facility consented to participate. Recruitment occurred at LDH and LMH from November 2014 to January 2015. The procedures for recruitment and enrollment into the study were as follows: 1) project manager asked permission to contact selected ART patients using contact information provided in the ART enrollment list; 2) project manager met prospective participants at the health facility to explain the study and obtain consent; and 3) if participant gave consent, that participant was enrolled into the study and the project manager administered the study informed consent form. For participants who expressed interest in the project but would like to further consider their participation, the project manager obtained their oral consent to contact the participants no sooner than three days after the first consent discussion. After obtaining consent and signing the informed consent form, the project manager administered the baseline survey. For participants in the intervention health facility, the project manager scheduled the dates for the intervention training and communicated this information to treatment participants.

Research Design

The pilot *Health & Wealth* project used a non-equivalent groups design (NEGD). NEGD is a pre- and post-test quasi-experimental design with treatment and comparison groups. In this study, two comparable health facilities in Lundazi District were selected. LMH was assigned as the intervention or treatment site. LDH was assigned as the comparison site. Although the two selected health facilities were as similar as possible (based on observed variables) to compare objectively the treated group with the non-treated group, the lack of random assignment did not

ensure that both sites were equivalent in both observed and unobserved characteristics. Nonetheless, the quasi-experimental design allowed clear establishment of: 1) temporal precedence (i.e., the intervention occurred before the measurement of key outcomes); and 2) association between participation in *Health & Wealth* and key outcomes through the use of appropriate statistical techniques. Further, the NEGD of *Health & Wealth* addressed methodological weaknesses in previous studies of IHLPs. For instance, three published IHLP studies (Datta & Njuguna, 2009; Pandit et al., 2010; Wagner, Rana et al., 2012) did not have a control group, and two studies (Datta & Njuguna, 2009; Wagner, Rana et al., 2012) lacked pretest observations.

The choice of health facilities as the unit of assignment was a purposeful research design component because of the nature of the project and its target population. ART patients in Zambia are registered at a health facility where they receive treatment and go for their follow-up clinic and pharmacy visits. In other words, ART patients are nested within health facilities. The assignment of health facilities into treatment or comparison site addressed the limitations of assignment of individual patients within the same health facility into treatment or comparison group. For instance, it may not be practical to isolate each ART patient who receives treatment from the same health facility and to give the same patient a unique treatment, for diffusion of treatment or resentful demoralization (on the part of those who did not receive treatment) might occur. In other words, to control for treatment diffusion and resentful demoralization, one health facility (LMH) was assigned as treatment site and the other health facility (LDH) was assigned as comparison site. (Appendix D outlines the selection process of health facilities and describes the two health facility sites.) The study design was approved by the ethics review committee at the University of North Carolina at Chapel Hill and the University of Zambia. An approval to conduct research activities in Zambia was also obtained from the Ministry of Health, as well as letter of support from the District Health and Medical Office in Lundazi District.

Data Collection

The dissertation used data gathered from survey and health facility records. Data collection periods differed depending on the type of method. Survey data came from the baseline (pretest) survey conducted between December 2014 and January 2015, and a brief midpoint survey conducted in September 2015. In addition, health facility records or clinical data were abstracted from LDH and LMH at baseline. Baseline clinical data collection occurred between January and March 2015, or before the start of the intervention. No midpoint clinical data abstraction was conducted. All 101 participants had baseline survey and clinic data. Eighty participants were surveyed at midpoint, which equated to 79% data collection retention.

Each data collection method gathered different types of data. First, the baseline survey gathered data on patient demographics and household social and economic characteristics, including food insecurity. Patient demographics included age, gender, marital status, occupation, and education level. Household social and economic characteristics included household size, income, asset ownership, financial status, and food insecurity. Baseline survey also included questions on mental health status (e.g., perceived stress), self-perceived health, accessibility of health facilities (e.g., distance, travel time and mode of transport), and barriers to HIV treatment adherence (particularly, pill taking and clinic attendance). Second, the brief midpoint survey collected data on key outcome variables, including food insecurity. Both baseline and midpoint surveys also collected ART adherence data using the visual analog scale. Third, baseline clinical records were reviewed to obtain ART-related information (e.g., treatment start date, treatment duration, treatment regimen, timing of pharmacy/medication pick-up) and patient health data (e.g., weight, BMI, CD4 count, and WHO stage). Table 2 lists the data collection method for study constructs and survey items to measure key variables.

Measures

ART adherence. ART adherence was measured using participant self-reported data and pharmacy record. Patient self-reported data were assessed using ART adherence visual

analog scale. The visual analog scale (VAS) assessed adherence during the past 30 days; and was represented with a box that corresponded to the percentage of prescribed doses taken. The percentages were illustrated in intervals of 10, from 0 to 100. Participants were asked to place an “X” inside the box above the point (or percentage) showing the best guess about how much of the current antiretroviral medications were taken in the past 30 days.

Pharmacy records, or pharmacy refill information, referred to the timing of ARV prescription pick-up. Pharmacy refill data can serve as a surrogate adherence measure by providing the dates on which antiretroviral medications were dispensed. In the event that refills are not obtained in a timely manner, it is assumed that ART patients are not taking their medications between refills or are missing doses in a way that allows medication to last longer than it should (Steiner & Prochazka, 1997). The pharmacy adherence measure in this dissertation was based on a variation of the medication possession ratio (MPR), a measure of the proportion of days an ART patient possessed his or her medications relative to the total amount of time between two ARV prescription pick-ups (McMahon, Jordan et al., 2011). The MPR was derived from pharmacy data obtained from SmartCare, which collects HIV treatment information at all public ART sites in Zambia. Consistent with prior studies (e.g., Hong et al., 2014; Musumari et al., 2014), MPR was calculated as $1 - (\text{number of days late for ARV pick-up} / \text{total number of days between the two most recent ARV pick-ups})$, expressed as a percentage. The number of days late was determined by subtracting the date of actual pharmacy visit from the scheduled pharmacy visit (i.e., when ART patients are due to pick up their prescription so they will not run out of medications). Pharmacy records from the first and second quarters of 2015 were analyzed to calculate baseline MPR. Follow-up MPR was not available because pharmacy records were not abstracted at the time of midpoint survey data collection.

Despite limitations of self-report measures, self-reported ART adherence measures have been shown to perform well (i.e., no evidence of significant overestimation) in comparison with other more objective adherence measures such as biological markers and pharmacy refill data in

resource-rich and resource-poor settings (Duong et al., 2001; Kabore et al., 2015; Murri et al., 2000; Reynolds et al., 2007; Ross-Degnan et al., 2010; Simoni et al., 2014). Pharmacy records have also been shown to be highly associated with biological markers of adherence among ART patients in SSA (Henegar et al., 2015; Rougemont, Stoll, Elia, & Ngang, 2009), and to outperform self-reported methods in predicting ART-related outcomes (Grossberg, Zhang, & Gross, 2004; McMahon, Jordan et al., 2011; Sangeda et al., 2014). In addition, both adherence measures in this dissertation are commonly used measures of ART adherence in studies conducted in SSA (e.g., Court et al., 2014; Haberer et al., 2012; Olds et al., 2015; Wu et al., 2014), including studies on food insecurity and ART adherence (Hong et al., 2014; Musumari et al., 2014; Weiser et al., 2014). Furthermore, the use of more than one adherence measure may increase the validity of ART adherence data.

To examine the association between optimal ART adherence and food security, I created binary adherence variables using data from the VAS and MPR. Consistent with the definition of ART adherence (i.e., amount of medications taken divided by the amount of medications prescribed), optimal ART adherence was defined primarily as $\geq 95\%$ of scheduled doses taken (Paterson et al., 2000; Ickovics et al., 2002). In other words, participants were adherent if they took $\geq 95\%$ of prescribed doses, and non-adherent if they took $< 95\%$ of prescribed doses. Similarly, patients with adherence levels of $\geq 95\%$ based on MPR were categorized as optimally adherent, and patients with adherence levels of $< 95\%$ based on MPR were categorized as non-adherent (Paterson et al., 2000; Musumari et al., 2014). With this definition, optimal ART adherence (based on self-report and pharmacy record) was coded *0* if adherence level was below 95%, and *1* if adherence level is $\geq 95\%$.¹¹ However, other studies have shown that adherence level of $\geq 80\%$ or $\geq 90\%$ may be sufficient to achieve optimal outcomes (Kobin & Sheth, 2011; Shuter et al., 2007; Viswanathan et al., 2015). Based on data distribution, I used the $\geq 80\%$ and $\geq 90\%$

¹¹ For the visual analog scale, the primary optimal adherence definition of $\geq 95\%$ of prescribed doses taken is equivalent to a 100% of prescribed doses taken because the percentages illustrated in the visual analog scale were in intervals of 10 – from 0 to 100.

adherence levels as sensitivity models or alternative definitions of optimal adherence.¹² For these additional models, suboptimal adherence (or adherence level below a particular threshold) was coded 0 and optimal adherence (or adherence level at or above a particular threshold) was coded 1. For this dissertation, baseline and follow-up VAS scores and baseline MPR were obtained.

Food security. Food security or household food access was measured using a revised version of the Household Food Insecurity Access Scale (HFIAS; Coates et al., 2007).¹³ The revised HFIAS consisted of nine items that asked respondents the frequency of experiencing different conditions and degrees of food insecurity within the past four weeks (or 30 days). Response options for the nine items ranged from 0 (*never*) to 3 (*often*). Sample HFIAS items included: how often did you or any household members have to eat a limited variety of foods due to a lack of resources, and how often was there ever no food to eat of any kind in your household because of lack of resources to get food. Baseline and follow-up household food security data were collected. Individual indicators of the HFIAS are listed in Table 6.

I calculated three types of food insecurity indicators using HFIAS. These indicators included conditions, scale score, and prevalence (Coates et al., 2007). First, household food insecurity access-related conditions measured the percentage of households experiencing a specific food insecurity condition at any level of frequency or severity. These conditions referred to items 1 to 9 in the HFIAS. Second, HFIAS score was a continuous measure of the degree of food insecurity in the household during the recall period. HFIAS score was calculated by

¹² The alternative definitions of optimal adherence applied only to baseline MPR outcome data because there was not adequate variation in the baseline or follow-up VAS to create sensitivity models based on $\geq 80\%$ or $\geq 90\%$ thresholds.

¹³ The revised version combined the nine occurrence and nine frequency questions in the original HFIAS. Instead of asking a separate yes or no occurrence question (e.g., in the past four weeks, did you worry that your household would not have enough food?), the revised version incorporated the dichotomous occurrence question with the ordinal frequency question (e.g., in the past four weeks, how often did you worry that your household would not have enough food?). Response options for the revised items ranged from 0 (*never*) to 3 (*often*).

summing the score for all nine items. The higher the score, the more food insecurity the household experienced. Scores ranged from a minimum of 0 to a maximum of 27. Third, household food insecurity access prevalence (HFIAP) was a categorical measure of the different levels of household food insecurity. These levels include food secure, and mild, moderately and severely food insecure. Households were categorized as increasingly food insecure if they responded affirmatively to more severe conditions and/or experience those conditions more frequently. I created the different HFIAP levels using the definition and coding provided by Coates et al. (2007). For this indicator, food secure households were coded as 0, mildly food insecure 1, moderately food insecure 2, and severely food insecure 3. To categorize households as general food secure and food insecure, I created a binary variable based on the four categories of food insecurity, with food secure coded as 0, and mildly, moderately and severely food insecure coded as 1.

Treatment variable. A binary variable for treatment or IHLP participant was coded as 1 if the respondent receive ART at LMH (or the treatment site) and 0 if the respondent receive ART at LDH (or the comparison site).

Covariates. Covariates included patient demographics (age, gender, marital status, occupation, education level, and head of household status), household social and economic characteristics (household size, monthly income, and asset ownership), mental and physical health factors (perceived stress, self-perceived health, body mass index), physical accessibility of health facilities (distance and travel time), barriers to HIV treatment adherence (barriers to pill taking and barriers to clinic attendance), and ART-related characteristics (treatment duration, ART regimen, CD4 count). Descriptions of covariates, including how they were measured are provided in Table 3.

Analysis Plan

General analysis plan. Across all research questions, univariate statistics were examined for each variable included in the analysis. Frequencies and distributions were

examined for unusual values, skewness, and kurtosis. Bivariate analyses were conducted to identify differences in characteristics based on key dependent variables. For continuous outcome variables, *t* test or Wilcoxon rank-sum test was used. Nonparametric test was used when the assumption of normally distributed outcome variable was violated. For categorical outcome variables, χ^2 test was used. When predictor variables were continuous, bivariate analyses were performed using simple linear regression for continuous outcomes, and generalized linear regression for categorical outcomes. Multivariable regression models were then used to adjust for individual predictors or potential confounders. The level of statistical significance was set at $\alpha = .05$, two-tailed test. Diagnostic tests and residual analyses were also performed to determine whether multivariable statistical assumptions (for example, normal distribution of the dependent variable and residuals) were met. Normality of the dependent variable and residuals was checked. A formal test for heteroscedasticity was conducted using the Breusch-Pagan/Cook-Weisberg test. Tests for multicollinearity and influential data (using Cook's distance) were also conducted. In sum, univariate, bivariate and multivariable diagnostic tests were conducted to determine violations of statistical assumptions, to identify appropriate statistical tests, and to use suitable remedial procedures to address data violations.

Variable selection. I reviewed the literature to identify important covariates or potential confounders that should be included in the multivariable models. For instance, prior studies on determinants of food insecurity among PLHIV in SSA (e.g., McCoy et al., 2014; Nagata et al., 2012; Tsai et al., 2011) guided inclusion of explanatory variables in the multivariable models for research question 2. Also, previous research on factors that influence HIV treatment adherence among ART patients in SSA (e.g., Langebeek et al., 2014; Mills et al., 2006; Reda & Biadgilign, 2012) guided variable selection for research question 3. After the literature review defined an initial working set of variables, I used backward elimination (BE) to determine the final multivariable model. Literature suggests that BE procedures with a mild significance level criterion of $\alpha = .20$ are superior to other variable selection approaches

(Maldonado & Greenland, 1993; Sun, Shook, & Kay, 1996). In addition, variables that changed the coefficient for key predictors by more than 20% when eliminated were kept in the final model as these variables may provide necessary adjustment of the effect of the remaining variables in the model (Hosmer, Lemeshow, & Sturdivant, 2013). These model-building strategies were used as an addition to clear and careful review of the scientific literature. Purposeful variable selection may be a more efficient method when the focus is on risk factor modeling and not solely on prediction. All analyses were conducted using Stata 14 (StataCorp, 2015).

Analysis of missing data. Missing data are a common occurrence in research and can alter statistical results and conclusions. Missing data lead to reduction in sample size and can also result in biased parameter estimates. In order to address potential issues related to missing data, missing data were handled using multiple imputation. Multiple imputation (MI) is generally recognized as a more appropriate method for missing data analysis compared with traditional methods such as complete-case analysis (or listwise deletion), mean substitution and regression imputation (Allison, 2002; Enders, 2010; Little & Rubin, 2014).¹⁴ Traditional methods treat imputed data as if they are real or observed data, and ignore inherent uncertainty in imputed values (and that imputations are only estimates). Consequently, traditional methods often lead to biased parameter estimates and usually results in small standard errors (Allison, 2002). MI addresses limitations of traditional methods through three steps (Allison, 2002; Enders, 2010). First, MI introduces random variation into the imputation process and generates multiple data sets, each data set with different imputed values. Second, MI performs analysis (e.g., regression) on each imputed dataset separately. Third, MI combines the results into a single set of parameter estimates, standards errors, and test statistics.

¹⁴ In addition to multiple imputation, another recommended method of handling missing data is full information maximum likelihood (FIML).

Missing data analysis using multiple imputation included several steps, each undertaken separately. First, I explored missing-data patterns. I examined the presence of missing data, proportion of missing data and patterns of missing values. For instance, 12% of baseline ART adherence using the 30-day visual analog scale was missing. Similarly, 21% of follow-up outcome variables (food insecurity and ART adherence) were missing. Second, I explored missing-data mechanisms or the process that generated missing values. Missing data mechanisms generally fall into three categories: missing completely at random, missing at random and missing not at random. Using the steps outlined by Marchenko and Eddings (2011), results of diagnostic tests suggested that the missing at random (MAR) assumption may be reasonable. Missing data are considered to be MAR, a less restrictive assumption, if other variables in the dataset can be used to predict missingness on a given variable. MI generally assumes that missing data are at least missing at random.

Third, I built an imputation model based on best practices suggested in the literature (e.g., Bouhlila & Sellaouti, 2013; Enders, 2010; Graham, 2009; Rose & Fraser, 2008; White, Royston, & Wood, 2011). The first task in building an imputation model was to identify potential imputation variables. All selected variables were at least minimally associated with the variables containing the missing values (Allison, 2002, Rubin 1996). The imputation model also included dependent variables (Allison, 2002; Moons, Donders, Stijnen, & Harrell, 2006, von Hippel, 2007), although MI programs (such as in Stata) make no distinction between independent and dependent variables and only requires the analyst to specify a set of input variables. In addition, I included auxiliary variables (or variables in the multiple imputation model that were not in the planned analysis). Building a more general imputation model compared with a specific analytical model captures more associations between the variables (Enders, Dietz, Montague, & Dizon, 2006; Graham, 2009).¹⁵ However, given the large number of potential variables, the

¹⁵ I used the same imputation model for research questions 2 and 3. In addition to the imputation model for research questions 2 and 3, I included the follow-up data on food insecurity, ART adherence and perceived stress to build the imputation model for research question 4.

relatively small sample size of the data and to ensure model convergence, the final imputation model contained variables to be used in at least one of the analyses in this dissertation.¹⁶

The second task in building an imputation model was to specify the method for creating MI datasets. The two common approaches are the multivariate normal model and the chained equations approach. MI datasets were created by imputation using the chained equations approach, sometimes referred to as ICE or MICE (multiple imputation by chained equations).¹⁷ Unlike the multivariate normal approach, ICE does not assume multivariable normal distribution and can be used to impute different types of variables such as categorical, ordinal and count (van Buuren, 2007; White et al., 2011). ICE can use a linear regression to impute continuous variables, a logistic regression to impute binary variables, ordinal logistic regression to impute ordered-categorical variables, a negative binomial regression to impute count variables, and so on. In other words, ICE fits better with the current dataset which contains several types of variables that do not necessarily follow a normal distribution. In addition to its flexibility, ICE involves a series of univariate models (rather than a large single model) and fills in the data on a variable-by-variable basis by specifying an imputation model per variable (van Buuren, 2007; van Buuren et al., 2006). However, unlike the multivariate normal model, ICE lacks a strong theoretical rationale (Lee & Carlin, 2010). A more detailed description of this approach can be found in Raghunathan et al (2001), van Buuren (2007), and van Buuren et al (2006).

After selecting ICE as the imputation approach, the next step was to select the number of imputations (m). Previously, small values of m (between 3 and 10) were considered sufficient to

¹⁶ This imputation model is different from a model that contains only variables to be used in a specific analysis. For instance, the variables distance to health facility and travel time to health facility were not used to examine determinants of food insecurity among ART patients (research question 2). However, these two variables were included in the imputation model, and later used as covariates when I examined the relationship between food insecurity and ART adherence (research question 3).

¹⁷ This approach is also known as sequential regression imputation (Raghunathan, Lepkowski, Van Hoewyk, & Solenberger, 2001) and fully conditional specification (van Buuren, Brand, Groothuis-Oudshoorn, & Rubin, 2006).

yield unbiased results (Rubin 1987; Schafer, 1997; Schafer & Olsen, 1998). However, recent developments in this field (e.g., Graham, Olchowski, & Gilreath, 2007) have recommended larger values of m (than has previously been required) to yield accurate statistical results. In addition, using many more imputations can decrease multiple imputation standard errors, improve power and allow more accurate multiparameter significance tests (Enders, 2010). Based on the literature, a minimum of 20 imputed datasets seems to be a good rule of thumb for many real-world situations (Graham et al., 2007; Enders, 2010). Following best practices in the literature, I selected 20 as the number of imputations. I also tested the sensitivity of results to the number of imputations by generating additional MI models with 5 (small) and 50 (large) datasets. For research question 4 or the impact data analysis, I also created a multiply imputed dataset with $m = 100$. After selecting the number of imputations (which was the last step in building an imputation model), I implemented MICE in Stata using the *mi impute chained* command. For the univariate models, I used linear regression to impute continuous variables and ordinal logistic regression to impute ordered-categorical variables. After imputation, I checked the imputed datasets for errors, including whether all incomplete values were successfully and correctly imputed. Finally, I used Stata's *mi estimate* commands to conduct post-estimation tests such as linear and logistic regressions.

Research question 1. To assess the prevalence of food insecurity (at baseline and follow-up) in a sample of ART patients in Lundazi District, I used the Household Food Insecurity Access Prevalence status indicator (Coates et al., 2007). The HFIAP indicator categorized households as food secure and food insecure. Also, the HFIAP indicator classified households into four levels of food insecurity: food secure, mildly food insecure, moderately food insecure, and severely food insecure. The four food security categories were created sequentially to ensure that households were classified according to their most severe response, and were generated based on the recommendations of the developers of the HFIAS (Coates et al., 2007). The categories were coded as follows: 0 = food secure, 1 = mildly food insecure, 2 =

moderately food insecure, 3 = severely food insecure. For instance, a household was classified as severely food insecure if the respondent answered *often* to items number 5 or 6, or answered *rarely, sometimes* or *often* to items number 7, 8 or 9. A binary variable was also created to classify households into general food secure and food insecure. This variable was based on the original four categories, with food secure coded as 0, and mildly, moderately and severely food insecure coded as 1. Further, the prevalence of different levels of household food insecurity was calculated by dividing the number of households that belong in each food insecurity category with the total number of households with a household food insecurity category, expressed as a percentage. In addition to prevalence, I examined household food insecurity access-related conditions, or the proportion of households that reported experiencing various food insecurity conditions at any time during the recall period. Household food insecurity conditions were calculated by dividing the number of households with a “non-never” response to a specific occurrence question by the total number of households that responded to the same question, expressed as a percentage.

Research question 2. To examine the factors associated with higher risk of food insecurity among ART patients in Lundazi District, I used ordinary least squares (OLS) regression, a method for estimating unknown parameters in a linear regression model. For k explanatory variables and $i = 1, \dots, n$, the regression model is:

$$Y_i = \beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \dots \beta_k X_{ik} + \varepsilon_i, \quad (3.1)$$

where Y_i is the value of the response variable for individual i , $\beta_0, \beta_1, \beta_2, \dots, \beta_k$ are the regression coefficients or parameters, $X_{i1}, X_{i2} \dots, X_{ik}$ are known constants or values of the predictor variables for individual i , and ε_i is a random error term (with mean $E\{\varepsilon_i\} = 0$ and variance $\sigma^2\{\varepsilon_i\} = \sigma^2$; and ε_i and ε_j are uncorrelated so that their covariance is 0; Kutner, Nachtsheim, & Neter, 2004). For research question 2, the regression model was linear in the parameters because no parameter was an exponent or was multiplied or divided by another parameter, and linear in the predictor variables because all predictor variables appeared only in the first power.

To find “good” estimators of the regression coefficients $\beta_0, \beta_1, \dots, \beta_k$, the OLS method considers the deviation of the observed value (Y_i) from its expected value:

$$Y_i - (\beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \dots \beta_k X_{ik}). \quad (3.2)$$

In particular, the OLS method requires that we consider the sum of the n squared deviations.

This criterion is denoted by:

$$Q = \sum_{i=1}^n (Y_i - \beta_0 - \beta_1 X_{i1} - \beta_2 X_{i2} - \dots \beta_k X_{ik})^2. \quad (3.3)$$

The objective of the method of least squares is to find estimates b_0, b_1, b_2 , and b_k for $\beta_0, \beta_1, \beta_2, \dots, \beta_k$, respectively, for which Q is a minimum for the given sample observations $(X_1, Y_1), (X_2, Y_2), \dots, (X_n, Y_n)$. These estimates will provide a “good” fit of the linear regression function. More importantly, OLS estimators are the best linear unbiased estimators. Based on the Gauss-Markov theorem, the OLS estimators b_0, b_1, b_2 , and b_k , given the assumptions of the classical linear regression model, are unbiased and have minimum variance among all unbiased linear estimators. Because the sample parameters are unbiased estimators, neither estimator tends to systematically overestimate or underestimate. Further, because these estimators have minimum variance, they are more precise than any estimators belonging to the class of unbiased linear estimators (Kutner et al., 2004).

Dependent variable and analytical plan. The dependent variable of interest was (baseline) household food insecurity measured by the HFIAS score, or a continuous-level measure of inadequate access to food. Given the research question, multivariable OLS regression was used to analyze the data because this method allowed me to examine more than one explanatory variable working simultaneously to predict and explain household food insecurity among ART patients in rural Zambia. OLS regression was also appropriate given the type of data used: a continuous outcome variable and continuous and categorical explanatory variables. Results of the diagnostic tests and residual analysis showed that the dependent variable and residuals were reasonably normally distributed. In addition, results indicated absence of heteroscedastic, highly collinear, and influential data in the final model. However, I

used robust regression to address non-normality of some predictor variables (for example, livestock ownership). Although robust regression produces the same R^2 , b 's, and β s, it has standard errors that do not assume normality.

Analytical models and predictors of food insecurity. I estimated four models using multivariable linear regression. The first model estimated household food insecurity score by controlling for demographic characteristics of ART patients (for example, age, gender, marital status, occupation, education level, head of household status, and geographic residence). The second model took into account social and economic variables (including household size, financial situation status, household monthly income, asset ownership, frequency of saving, and presence of debts) in addition to the covariates introduced in the first model. For this analysis, asset ownership referred to four different types of assets – land, mode of transport, livestock, and household possessions. The results of the second model indicated the extent to which food insecurity score could be explained by household socioeconomic characteristics. The third model added health characteristics of ART patients (including perceived stress, ART duration, and health perception), after demographic, social and economic characteristics. The fourth model used backward elimination to determine the final multivariable model. Descriptions of how the explanatory variables were measured are explained in Table 3.

Research question 3. To investigate the relationship between food insecurity and optimal ART adherence among ART patients in Lundazi District, I used generalized linear regression. Because optimal adherence outcomes were binary variables (non-adherent or adherent), I used logistic regression to estimate the relationship between food insecurity and treatment adherence. In logistic regression, the values for the dependent variable (in this case, ART adherence) are presented as probabilities that range between 0 and 1. Logistic regression assumption differs from OLS regression where the relationship is considered linear. When applying OLS method to binary dependent variable, non-normal error terms, heteroscedasticity

(i.e., the error variance is not the same for all observations), and out-of-range predicted values (i.e., outside the $[0, 1]$ interval) become issues (Allison, 2012; Kutner et al., 2004).

Although violations of assumptions of homoscedasticity and normality of error terms are not necessary to obtain unbiased estimates, violation of the homoscedasticity assumption has two undesirable consequences: 1) coefficient or parameter estimates are no longer efficient (i.e., there are alternative estimation methods with smaller standard errors); and 2) the standard error estimates are no longer consistent estimates of the true standard errors (i.e., estimated standard errors can be biased) (Allison, 2012). Consequently, test statistics can also be biased because standard errors are used in calculating the same test statistics. In other words, the bias results in inaccurate significance levels and confidence intervals. Assumptions of the linear model also become implausible when the dependent variable is binary. When estimating a linear probability model by OLS, predicted values generated from the model can be outside the $(0, 1)$ range. However, it is impossible for the true values (in this case probabilities) to be less than 0 or greater than 1.

One of the alternative methods (with better statistical properties and theoretical foundation) to linear probability model is the logistic regression model (or the logit model). With logistic regression model, the probability is transformed so that it is no longer bounded. A logit link function, defined as $g(\mu) = E(V) = \log_e \left(\frac{p}{1-p} \right)$, is used to transform the variable. The transformed variable through the logit link function then becomes a linear function of the predictor variables. For multivariable models with k explanatory variables and $i = 1, \dots, n$ individuals, the logit model is

$$\log \left[\frac{p_i}{1-p_i} \right] = \beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \dots + \beta_k X_{ik}, \quad (3.4)$$

where p_i is the probability that $y_i = 1$, $\beta_0, \beta_1, \beta_2, \dots, \beta_k$ are the regression coefficients or parameters, and $X_{i1}, X_{i2}, \dots, X_{ik}$ are known constants or values of the explanatory variables for individual i .

The expression on the left-hand side, $\log \left[\frac{p_i}{1-p_i} \right]$, is called the log-odds, or the ratio of the

probability of having the event over the probability of not having the event. We can solve the logit equation for p_i to obtain:

$$p_i = \frac{\exp(\beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \dots + \beta_k X_{ik})}{1 + \exp(\beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \dots + \beta_k X_{ik})} \quad (3.5)$$

The equation can be simplified further by dividing both the numerator and denominator by the numerator itself:

$$p_i = \frac{1}{1 + \exp(-\beta_0 - \beta_1 X_{i1} - \beta_2 X_{i2} - \dots - \beta_k X_{ik})} \quad (3.6)$$

This equation has the desired property that no matter what values are substituted for the β 's and the X 's, p_i will always be a number between 0 and 1 (Allison, 2012). Unlike the linear regression model, the logistic model does not have an error term. Further, unlike OLS regression which minimizes errors, logistic regression uses the maximum likelihood (ML) method. ML method maximizes the probability or likelihood of reproducing the sample data. In other words, the coefficients are chosen in such a way that by applying these coefficients an analyst will best reproduce the sample data.

Dependent variable. In this research question, the dependent variable was ART adherence. ART adherence was measured using a visual analog scale and pharmacy dispensation information. Both measures were collected at baseline. VAS was used to assess self-reported one-month adherence. Pharmacy refill data, considered a surrogate marker of medication adherence, assessed pharmacy adherence using medication possession ratio. (Description of the adherence measures is provided in the measures section of this chapter.) The primary definition of optimal adherence was set at the $\geq 95\%$ threshold for both VAS and MPR. Alternative optimal adherence definitions were also examined. These alternative definitions were set at the $\geq 90\%$ and $\geq 80\%$ thresholds. However, alternative definitions were created only for MPR because there was adequate variation in the baseline MPR data to generate different

¹⁸ $\exp(x)$ is the exponential function, equivalent to e^x . e is the exponential constant, with its defining property: $\log(e^x) = x$ (Allison, 2012).

outcome specifications. On the contrary, there was not sufficient variation in the baseline VAS to create sensitivity models based on $\geq 80\%$ or $\geq 90\%$ thresholds.

Key explanatory variable. The main explanatory variable of interest was (baseline) food insecurity. Food insecurity was a continuous variable estimated using the composite score derived from HFIAS. The higher the score, the more food insecurity the household experienced. Additional analyses were also performed to assess robustness of the relationship based on various definitions of the key predictor variable (food insecurity). I created five different food insecurity variables based on the continuous-level food insecurity scores and categorical prevalence distribution. First, I used the household food insecurity access prevalence, which was a categorical measure of the four different levels of household food insecurity (food secure, mildly food insecure, moderately food insecure, and severely food insecure). Based on the distribution of prevalence categories, I created three dummy variables. The first dummy variable was coded 0 for *moderately or severely food insecure* and 1 for *food secure or mildly food insecure*. The second dummy variable was coded 0 for *not moderately food insecure* and 1 for *moderately food insecure*. The third dummy variable was coded 0 for *not severely food insecure* and 1 for *severely food insecure*. In this analysis, the reference group was respondents who were food secure or mildly food insecure. Second, I created a dichotomous variable that categorized the sample as either food insecure or food secure. This variable was coded 0 if the respondent was food secure or 1 if the respondent was food insecure, regardless of severity. In other words, mildly, moderately, and severely food insecure respondents were all classified as food insecure. Third, I created a binary variable that grouped the sample as either severely food insecure or not severely food insecure. This variable was coded 0 if the respondent was not severely food insecure (or either food secure, mildly food insecure, or moderately food insecure), or 1 if the respondent was severely food insecure. Fourth, I created a dichotomous variable that classified the sample based on the mean food insecurity score. This variable was coded 0 if a respondent's food insecurity score was below the mean value, and coded 1 if food insecurity score was at or

above the mean value. As illustrated in Table 5, the baseline mean food insecurity score was 14.43 ($SD = 7.86$). Fifth, I generated another binary variable that grouped the sample based on the median food insecurity score. Consistent with mean food insecurity variable, this variable was coded 0 if food insecurity score was below the median value, and coded 1 if food insecurity score was at or above the median value. For the 101 respondents, the baseline median food insecurity score was 13.

Specification of analytical models. Based on various definitions and measures of ART adherence and food insecurity, I estimated 24 models using multivariable logistic regression. I ran separate models for each type of adherence measure (i.e., baseline VAS and baseline MPR). For MPR, I ran separate models for each optimal adherence level (i.e., $\geq 95\%$, $\geq 90\%$, and $\geq 80\%$). I also conducted separate analysis for each of the six specifications of the food insecurity variable (i.e., continuous-level scores, categorical prevalence indicator, dichotomous food insecurity, severe food insecurity, and average scores [both mean and median]). The first six models estimated the association between food insecurity and optimal ART adherence at the $\geq 95\%$ threshold based on the visual analog scale. The next six models estimated the association between food insecurity and optimal ART adherence at the $\geq 95\%$ threshold based on medication possession ratio. The following six models estimated the association between food insecurity and optimal ART adherence at the $\geq 90\%$ threshold based on medication possession ratio. The last six models estimated the association between food insecurity and optimal ART adherence at the $\geq 80\%$ threshold based on medication possession ratio. In sum, I used different ART adherence measures, optimal adherence levels, and specifications of food insecurity variable to check the robustness of findings and assess sensitivity of results to variation of model specification. In all these models, I used the baseline food insecurity and adherence (VAS and MPR) data to investigate the relationship between food insecurity and treatment adherence.

Selection of covariates. Given the study's smaller sample size and relatively high number of known and observed covariates that affect ART adherence in SSA, identification of a more parsimonious model was important to avoid over parameterization and maintain consistency of findings across models. In addition to a careful review of the scientific literature to identify barriers and facilitators of optimal ART adherence, I used the model-building strategies outlined in the variable selection plan. Furthermore, for binary outcomes, I used the more relaxed rule of at least 5 observed events per predictor variable that was entered into a logistic regression model (Vittinghoff & McCulloch, 2007).

Results of the purposeful variable selection strategy are presented in Appendix E. Tables 15 and 16 in Appendix E present results of the variable selection strategy based on complete-case analysis using visual analog scale and medication possession ratio, respectively. Tables 17 and 18 in Appendix E list results of covariate selection based on multiple imputation model using visual analog scale and medication possession ratio, respectively. Findings from complete-case analysis and multiple imputation methods were identical. However, the number of selected covariates differed between the two types of ART adherence measures. From an initial list of 25 variables, five covariates were retained and included in the multivariable logistic regression models that examined the relationship between food insecurity and ART adherence using baseline visual analog scale. The covariates in the multivariable logistic regression models included occupation, geographic residence, asset ownership (transportation and livestock), and health perception. Furthermore, ten covariates were included in the multivariable logistic regression models that examined the relationship between food insecurity and ART adherence based on medication possession ratio. These covariates were education, financial status, household income, ownership of transport-related assets, debt, perceived stress (coping and distress factors), treatment duration, and access to health facilities (distance and travel time to

reach a health facility).¹⁹ After the final set of covariates was identified, I added the key explanatory variable of interest (food insecurity) to the model.

In addition, results of the diagnostic tests showed that a harmful multicollinearity problem did not exist in all models ($VIF < 10$). Using Cook's distance statistic, result showed no influential data. However, I used robust regression to address non-normality of some predictor variables (for example, livestock ownership).

Research question 4. To evaluate the impact of participation in an IHLP on food security and ART adherence, I used bivariate and multivariable analysis to compare the outcomes for the treated group with the comparison group. For research question 4, the unit of analysis was the individual. Treatment effects were examined using intention-to-treat (ITT) analysis. ITT analysis includes outcomes of all treatment participants – whether they received all or part of the intervention – and compared to the outcomes of all comparison participants (Fraser, Richman, Galinsky, & Day, 2009). ITT is generally analogous to average treatment effect and evaluates the overall effectiveness of an intervention (Sobel, 2005). Although estimate of treatment effect based on ITT analysis is generally smaller than that of other methods (e.g., efficacy subset analysis; Sobel, 2005), ITT analysis is considered a solution to some of the practical issues that arise in intervention research, including noncompliance and treatment attrition (Frangakis & Rubin, 1999). ITT analysis also preserves the original sample size, which is crucial in this pilot study because of its small sample size. Further, a better application of the ITT approach is possible if complete follow-up or outcome data are available for all subjects (Gupta, 2011; Lachin, 2000). In cases when treatment participants withdrew from treatment, these participants were still tracked and their follow-up data were collected in order to conduct a “true” all-inclusive, intent-to-treat analysis.

¹⁹ For adherence based on medication possession ratio data, I used a more conservative significance level criterion ($\alpha = .10$) in the BE procedure to select covariates for the final model.

Treatment and outcome variables. For the impact analysis, the key independent variable was participation in *Health & Wealth* intervention – coded as 1 if the subject was from LMH (or the treatment site) and 0 if the subject was from LDH (or the comparison site). The two outcome variables of interest were food insecurity and ART adherence. Baseline and follow-up food insecurity were measured using the household food insecurity access scale. Food insecurity was a continuous variable. Baseline and follow-up ART adherence were measured using a visual analog scale. VAS assessed medication adherence within the past 30 days (or one month). Consistent with research question 3, optimal ART adherence based on VAS was a binary variable that classified ART patients as adherent ($\geq 95\%$ of prescribed doses taken) or nonadherent ($< 95\%$ of prescribed doses taken).²⁰

Analysis plan. The analysis plan for research question 4 included several steps, each undertaken separately. First, I conducted bivariate tests to examine whether key baseline characteristics (including food security and ART adherence) were comparable between treatment and comparison groups prior to intervention receipt. Second, I analyzed pretest and posttest outcome data to examine differences in the distribution of outcomes between treatment and comparison groups and to estimate impacts of *Health & Wealth*. I examined pretest and posttest outcome data between groups based on the regressor variable method, i.e., posttest observations adjusted for baseline measurement (Bonate, 2000; Finkel, 1995; Twisk, 2003). In the regressor variable method, Y_{i2} is regressed on both Y_{i1} and X_{i1} , where Y_{i1} and Y_{i2} are the responses of individual i at time points 1 and 2, respectively, and X_{i1} is the treatment variable. For the regressor variable method, I used simple linear regression for continuous dependent variable and logistic regression for binary dependent variable. Third, I estimated multivariable models that controlled for potential confounders on the relationship between *Health & Wealth*

²⁰ The alternative definitions of optimal adherence were not applicable because there was not adequate variation in the follow-up VAS to create sensitivity models based on $\geq 80\%$ or $\geq 90\%$ thresholds. Follow-up pharmacy records were not collected at the time of this dissertation writing, but will be collected at a later time point.

participation and key outcomes (food insecurity and ART adherence). For food insecurity and ART adherence, covariates were consistent with the final multivariable models in research questions 2 and 3. Multivariable extensions of linear and logistic regressions were used to estimate the models with multiple covariates. Fourth, I estimated the impacts of *Health & Wealth* using the treatment effects model to take into account nonrandom assignment and provide a more rigorous method to evaluate program effects. For multivariable models, the dependent variable was follow-up outcome data with baseline values added as covariates. All analyses were conducted using multiply imputed datasets.

Estimating treatment effects in observational data. Unlike experimental studies, drawing causal inferences in quasi-experimental or observational studies, such as *Health & Wealth* pilot study, is challenging because the lack of random assignment may create treatment and comparison groups that are imbalanced on observed and unobserved characteristics (Rosenbaum, 2002; Rubin, 2008). Consequently, any estimated association between treatment (in this case, *Health & Wealth* participation) and outcomes (in this case, food security and ART adherence) can be biased because of the imbalance, including in baseline characteristics, which may affect the outcome. In other words, because the pilot study lacked random assignment, an unbiased estimate of the treatment effect could not be obtained by directly comparing outcomes between the two groups. Issues common in observational studies such as selection bias can lead to biased estimates using conventional methods for data balancing including OLS regression or matching (Berk, 2004; Guo & Fraser, 2014). Because of selection bias common in quasi-experimental studies, more rigorous and efficient analytical methods to evaluate treatment effects using observational data have been developed and tested (e.g., Bang & Robins, 2005; Heckman, 1978, 1979; Rosenbaum & Rubin, 1983; Wooldridge, 2002).

Treatment effect model. Based on Heckman's sample selection model (1974, 1978), the treatment effect model is one example of an analytical method that offers a more rigorous

estimation of treatment effects using quasi-experimental data by correcting for selection bias (Maddala, 1983). Consistent with sample selection model, the treatment effect model emphasizes the importance of modeling explicitly the sample selection process. In quasi-experimental studies, the treatment effect model adjusts for heterogeneity of program participation (in this case participation in *Health & Wealth*) by taking into consideration covariates affecting selection bias. In other words, the sample selection process estimates the probability of a participant being in one of two conditions indicated by an endogenous dummy variable (e.g., program participation). In addition, the treatment effect model uses the probability of being assigned, for example, to one of two conditions to estimate coefficients of the regression model that determines the outcome variable. More formally, the treatment effect model is expressed in two equations (Guo & Fraser, 2014):

$$\text{Regression equation: } y_i = x_i\beta + w_i\delta + \varepsilon_i, \quad (3.7a)$$

$$\text{Selection equation: } w_i^* = z_i\gamma + u_i, w_i = 1 \text{ if } w_i^* > 0, \text{ and } w_i = 0 \text{ otherwise,} \quad (3.7b)$$

$$\text{Prob}(w_i = 1 | z_i) = \Phi(z_i\gamma) \text{ and}$$

$$\text{Prob}(w_i = 0 | z_i) = 1 - \Phi(z_i\gamma).$$

In the equations, y_i is the outcome variable; x_i is a vector of exogenous variables determining outcome y_i ; β is the regression coefficients; w_i is an endogenous variable; z_i is a vector of exogenous variables determining the selection process or the outcome of w_i^* ; $\Phi(\cdot)$ is the standard normal cumulative distribution function; and u_i and ε_i are error terms of the two regression equations and assumed to be bivariate normal, with mean zero and covariance matrix $\begin{bmatrix} \sigma_\varepsilon & \rho \\ \rho & 1 \end{bmatrix}$. Given sample selection and that w is an endogenous dummy indicator, the evaluation task in the treatment effect model is to use the observed variables to estimate the regression coefficients (β) while controlling for selection bias induced by nonignorable treatment assignment or selection bias (Guo & Fraser, 2014).

Furthermore, the regression equations described in 3.7a and 3.7b can be switched. By replacing w_i in Equation 3.7a with Equation 7.b, two different equations of the outcome regression are obtained (Guo & Fraser, 2014):

$$\text{when } w_i^* > 0, w = 1: y_i = x_i\beta + (z_i\gamma + u_i)\delta + \varepsilon_i, \quad (3.8a)$$

and

$$\text{when } w_i^* \leq 0, w = 0: y_i = x_i\beta + \varepsilon_i. \quad (3.8b)$$

Equations 3.8a and 3.8b also represent the two separate outcome models for each condition defined in the endogenous dummy (treatment) variable. For treated participants, the outcome model is described in Equation 3.8a, whereas for nontreated participants, the outcome model is illustrated in Equation 3.8b. In this context, I used the treatment effect model to estimate treatment effects (i.e., to test potentially causal relationships, conditional on observed covariates, between *Health & Wealth* participation and key outcomes). Treatment effect models were conducted using the maximum likelihood procedure. Two-step consistent estimates were also obtained to determine whether results were sensitive to estimation procedures.

Counterfactual framework. In the current study, each subject was assigned to either treatment or control group only, and thus only one outcome was observed for each subject (i.e., the outcome under the actual group assignment). To address the limitation of not having observed the outcome for each subject if the same subject was assigned to the other group, I applied the Neyman-Rubin counterfactual framework of causality (Neyman, 1923; Rubin, 1974; 1986; Imbens & Rubin, 2015). Because the counterfactual (or a potential outcome that would have occurred in the absence of the cause; Shadish, Cook & Campbell, 2002) is not observed in real data, the Neyman-Rubin counterfactual framework allows assessment of the counterfactual by evaluating the differences in mean outcomes between the treated and untreated groups (Guo & Fraser, 2014). The treatment effect can be defined as a mean difference:

$$\hat{\tau} = E(\hat{y}_1 | w = 1) - E(\hat{y}_0 | w = 0), \quad (3.9)$$

where $E(\hat{y}_0|w = 0)$ denote the mean outcome of individuals in the control group, and $E(\hat{y}_1|w = 1)$ denote the mean outcome of individuals in the treatment group. In this pilot study, the dilemma of not observing the outcomes for treated individual i in the condition of not having participated in *Health & Wealth* was resolved by examining the average outcome values for all subjects in the control group (i.e., those who did not receive the treatment). Similarly, if the comparison of the two mean outcomes leads to:

$$\hat{\tau} = E(\hat{y}_1|w = 1) - E(\hat{y}_0|w = 0) > 0, \quad (3.10)$$

or the mean outcome of all sample individuals who participated in *Health & Wealth* is higher than nonparticipants, then we can infer that *Health & Wealth* leads to positive increases in the outcomes of interest.

Covariates of livelihood security (sample selection process). The choice of (observed) covariates hypothesized to affect sample selection (in this case *Health & Wealth* participation) serves an essential role in the treatment effect model. Covariates were chosen based on review of the literature on livelihood security in resource-limited settings. Although few studies have focused exclusively on livelihood participation of ART patients, a review of the livelihood literature in the general population suggests that covariates of livelihood security in SSA are wide-ranging and include demographic, economic, and health characteristics.²¹ Consistently, gender, education, income, and asset ownership regardless of HIV status predict engagement in various livelihood or income-generating activities (Chowa, 2008; Fabusoro, Omotayo, Apantaku, & Okuneye, 2010; McCoy, Ralph, Wilson, & Padian, 2013; Pearson et al., 2013). Although women, in many cases, provide the majority of agricultural labor in SSA, they remain to have limited control over livelihood activities (Gibbs, Willan, Misselhorn, & Mangoma, 2012; McCoy et al., 2013). In addition, cash income is viewed as part of the male domain in many societies in SSA (Gladwin, Thomson, Peterson, & Anderson, 2001). Education

²¹ I limited the discussion of livelihood security covariates to variables that were measured at baseline, and thus were observed in the *Health & Wealth* study.

also determines livelihood security through its impact on an individual's ability to engage in various income-generating activities and diversify income sources (Reardon, 1997; Smith, Gordon, Meadows, & Zwick, 2001). Education provides skills and facilitates attitude changes that can be used to create or take advantage of livelihood opportunities. Accordingly, individuals with higher education levels have a higher likelihood of engaging in non-farm activities than those with lower education levels (Newman & Canagarajah, 1999). Among those engaged in farming activities, education contributes to better farm production and efficiency (Weir & Knight, 2004, 2007) and promotes innovation and decreases risk-aversion (Knight, Weir, & Woldehanna, 2003).

Economic resources such as income and assets also play an important role in predicting a household's ability to engage in different livelihood activities. In resource-limited settings, assets are important because they can be used as a capital to start an income-generating activity or as an income-diversification strategy, as well as a protective factor against economic shocks (Barrett, Carter, & Little, 2006; Carter & May, 1999; Chowa, 2008; Chowa, Masa, & Sherraden, 2012). For many households in resource-limited settings, assets that contribute to livelihood security include natural capital (e.g., land) financial capital or its substitutes (e.g., savings, household possessions, and livestock), human capital (e.g., education and health), and physical capital (e.g., transportation) (Bebbington, 1999; Ellis, 2000; Scoones, 1998).

Furthermore, health, particularly being HIV positive, influences an individual's involvement in livelihood activities. As explained in Chapter 1, being HIV positive negatively affects livelihood security primarily through reduced labor and physical productivity due to HIV-related illnesses, which in turn, decrease income and assets (Bachmann & Booyesen, 2006; Byron et al., 2007; Parker et al., 2009; Seeley et al., 2008). Also, ART treatment status (i.e., whether PLHIV is currently on ART or not) influences ability of PLHIV to engage in livelihood activities that require physical energy and stamina (Gillespie & Kadiyala, 2005; Samuels & Rutenberg, 2011). However, given *Health & Wealth* was targeted only to PLHIV on ART, all

participants shared the same HIV and treatment status and thus, both treated and untreated subjects were balanced on these health factors. Nonetheless, ART patients differed on other health and treatment-related factors that may affect their ability to engage in livelihood activities. These (observed) variables include treatment duration, treatment adherence, and CD4 count.

ART patients differed on the duration of their treatment, i.e., how long they have been receiving therapy. Research suggests that longer treatment duration allows ART patients to regain strength and energy and maintain positive physical and mental health (Weiser et al., 2012), which may allow them to engage in livelihood or income-generating activities. However, longer treatment duration by itself does not necessarily translate to strength and stamina recovery, as well as positive health without optimal adherence to ART. In addition to ART's positive impact on survival, adherence to ART helps improve physical and mental health status, which in turn, gives ART patients energy and stamina to engage in income-generating duties (Palar, Wagner, Ghosh-Dastidar, & Mugenyi, 2012; Weiser et al., 2012). Alternatively, ART patients with suboptimal adherence may not be able to fully participate in various livelihood activities because they may not have, for example, constant energy and adequate strength to begin and sustain livelihood responsibilities. In addition to treatment duration and adherence, CD4 count indicates whether an individual is healthy and how well the immune system is working. CD4 count is also a strong predictor of HIV progression (Gupta et al., 2011; Hogg et al., 2001; Weber et al., 2006), and higher CD4 count is a sign of good health. ART patients with low CD4 count may be less likely to engage in income-generating responsibilities because of their weak immune system and poor health conditions that may prevent them from engaging in income-generating activities compared with ART patients with normal and healthy CD4 count.

In summary, a review of the literature suggests a number of variables that may affect ART patients' participation and engagement in livelihood activities. These covariates of livelihood security included gender, education level, assets (landownership, ownership of

transport-related assets, livestock and household possession), and ART-related factors (such as treatment duration, medication adherence and CD4 count). These known covariates were measured at baseline, and were included in the selection equation of the treatment effect models.

Covariates of outcome variables. In addition to covariates of *Health & Wealth* participation, inclusion of (observed) covariates hypothesized to affect the outcome variables was an equally essential part of the treatment effect model. The covariates of outcome variables were consistent with the covariates in the conventional regression models (i.e., multivariable models that controlled for potential confounders on the relationship between *Health & Wealth* participation and key outcomes). For food insecurity, potential confounders were household size, financial situation, household income, asset ownership (transportation and household possessions), debt, and perceived stress (coping and distress). For ART adherence, potential confounders were occupation type, asset ownership (transportation and livestock), food insecurity, and health perception. All baseline values of the outcome variables were also included as a covariate.

CHAPTER 4: RESULTS

Descriptive Results

Table 4 presents descriptive statistics and bivariate analysis results. Column 2 lists the descriptive results. Column 3 describes the bivariate associations between food insecurity and selected characteristics. Column 4 shows the bivariate associations between ART adherence and key covariates. Prevalence of food insecurity in this sample of ART patients in Zambia is described in details in the next section. Column 3 results are presented in the section on risk factors associated with food insecurity. Column 4 results are explained in the later section on the relationship between food insecurity and ART adherence.

As illustrated in Table 4, ART adherence differed by adherence levels and measures. For instance, based on the baseline 30-day visual analog scale (VAS), 74% of the sample reported 100% adherence. Among the 26% of the sample who reported suboptimal adherence ($< 100\%$) on the 30-day VAS, 6% reported an 80% adherence level and 20% reported a 90% adherence rate. In addition, using pharmacy records (i.e., baseline medication possession ratio), 67% of respondents were optimally adherent at $\geq 95\%$ threshold and 33% had adherence level below 95%. When optimal adherence threshold was decreased to $\geq 90\%$ of all prescribed medications, a slightly higher percentage of respondents became adherent. The increase was 4% points, from 67% using a threshold of $\geq 95\%$ to 71% based on a threshold of $\geq 90\%$. Furthermore, optimal adherence rate at the $\geq 80\%$ threshold were 77%, and 23% were nonadherent. Unsurprisingly, the proportion of optimally adherent patients increased as the optimal treatment levels were lowered. In addition, comparison of the two adherence measures using the $\geq 95\%$ optimal adherence threshold indicated that ART adherence was higher based on the 30-day VAS (74%) contrasted with the medication possession ratio (67%). The differences may suggest sensitivity

of self-report adherence measures to bias, including overreporting or problem recalling real adherence levels. However, there was no significant difference between the two ART adherence measures.

In terms of demographics, the average age of the patients was 38. The youngest patient was 18 and the oldest was 50. Women (54%) outnumbered men (44%) in the study. Most patients were married; 25% were not married. Sixty-five percent had some primary education, and 35% obtained some secondary education or higher. Most ART patients (75%) in the study were involved in farming or farming-related occupations. In addition, nearly 7 in 10 patients were heads of household. The average household size was six individuals per household, which is higher than Zambia's national average of five household members. Most ART patients were income poor, with 70% reporting a household monthly income of K50 or less (or less than \$0.30 per day). Fifteen percent had average monthly income between K51 – K500 (or between \$0.30 and \$2.75 a day). The remaining 15% reported earning more than K500 per month (or more than \$2.75 per day). Using the World Bank's poverty line for low income countries of \$1.25 per day, an estimated 83% of the sample earned \leq \$1.25 a day, or roughly K250 or less.

In terms of asset ownership, 89% reported owning a plot of land. Bicycle was the most commonly-owned type of transport-related assets, with 21% of respondents reported owning one or two bicycles. After bicycles, ox carts and other types of motor vehicle were the second most commonly-owned mode of transport, with 5% of respondents reported owning an ox cart or a motor vehicle (such as cars or trucks). Livestock was more commonly owned than mode of transport. Chicken was the most commonly-owned livestock, with 46% of the sample reported raising one or more chickens. After chickens, cattle (12%) were the second most commonly-owned livestock, followed by pigs (9%) and goats (8%). Of all types of assets, household possessions were the most commonly-owned. Nearly half (48%) of respondents owned a cellular phone. Other household possessions that were owned by at least 20% of the sample included charcoal brazier (38%), radio (38%), and charcoal iron (26%). Eighteen percent owned

a television, and 9% owned a refrigerator. In terms of financial assets and liabilities, 64% were savers, i.e., they reported saving sometimes or more frequently, and 24% owed money.

In terms of health and treatment-related characteristics, the mean treatment duration was 26 months, and the median was 19 months. In other words, 50% of respondents have been on ART for at least 19 months at the time of baseline data collection. Most (81%) perceived their general health as good or better. Average (mean) score on the coping factor of the perceived stress scale was 9.44 points, with a minimum score of 0 and a maximum score of 16. Average score on the distress factor of the perceived stress scale was 7.45 points, with a minimum score of 0 and a maximum score of 24. In general, the sample had higher coping mechanisms than experiences of mental distress. In addition, respondents reported experiencing fewer barriers to pill taking and clinic attendance. The average score on the barriers to pill taking scale was 3 points, with possible scores ranging from 0 to 44. The average score on the barriers to clinic attendance was 5.30 points, with possible scores ranging from 0 to 48. The average distance between respondents' homes and the health facilities was 11.42 kilometers. Distances ranged from the nearest home at 0.3 kilometer to the farthest at 70 kilometers. The average travel time for respondents to reach the health facility was 110.19 minutes (or nearly two hours one way).

In terms of physical health, the average body mass index (BMI) was 22. Six percent of the sample was considered underweight or having a BMI of less than 18.5. The mean CD4 count at baseline was 471 cells per mm³. Thirty-nine percent of the sample had a CD4 count of at least 500 cells per mm³, which is considered a normal CD4 count of a healthy adult. On the other hand, 11% of the sample had a very low CD4 count of less than 200 cells per mm³. A very low CD4 count helps identify whether a person living with HIV has progressed to stage 3 infection (or presence of symptoms consistent with AIDS). In terms of treatment regimen, 97% of ART patients in the study were prescribed first-line ART and 3% were on second-line ART. Doses and schedule for all ARV prescriptions are outlined in Table 3. Lastly, in terms of pill burden, 22% of patients were taking more than one pill a day. Of the 78% who were prescribed a treatment

regimen of one pill once a day, all were given the drug combination of TDF + FTC + EFV (also commonly known by its brand name, Atripla).

Baseline characteristics of treatment and comparison groups. Table 5 presents results of bivariate tests that compared the baseline characteristics of Lumezi and Lundazi ART patients in the study. Bivariate results showed that Lumezi and Lundazi patients were not significantly different on their baseline household food insecurity scores. The proportion of food secure and food insecure patients were also not statistically different between Lumezi and Lundazi facilities ($p = 0.72$). Furthermore, Lumezi and Lundazi ART patients were not significantly different on their baseline ART adherence based on self-reported 30-day visual analog scale ($p = 0.50$). However, baseline ART adherence based on medication possession ratio indicated that Lumezi and Lundazi patients had significantly different optimal adherence levels. Using the $\geq 95\%$ threshold, 43% of Lumezi patients and 22% of Lundazi patients were nonadherent ($p < 0.05$). Baseline disparity increased between health facilities when using other adherence thresholds based on medication possession ratio. For instance, based on the $\geq 90\%$ threshold, 14% of Lundazi respondents were nonadherent compared to 43% of Lumezi patients. Similarly, 10% of Lundazi patients were nonadherent at the $\geq 80\%$ threshold contrasted with 37% of Lumezi patients. The percentage point differences between health facilities were 21, 29, and 27 points for the $\geq 95\%$, $\geq 90\%$, and $\geq 80\%$ optimal ART adherence thresholds, respectively.

In terms of key covariates, Lumezi and Lundazi patients were not significantly different on 14 of 27 baseline characteristics. As illustrated in Table 5, Lumezi and Lundazi ART patients were comparable or (statistically) balanced on the following variables: age, gender, marital status, education level, head of household status, household size, landownership, ownership of livestock, health perception, treatment regimen, body mass index, CD4 count, barriers to clinic attendance, and travel time to health facility. However, Lumezi and Lundazi participants differed significantly on 13 baseline factors. These covariates were type of occupation, financial status, household income, ownership of transport-related assets, ownership of household

possessions, saving behavior, presence of debt, treatment duration, perceived stress (coping and distress), pill burden, barriers to pill taking, and distance to health facility. These differences suggest that Lumezi and Lundazi participants were not balanced on these observed covariates.

Prevalence of Food Insecurity

Baseline household food insecurity. Ninety-three percent of the sample and their households reported food insecurity during the past 30 days prior to baseline data collection (between December 2014 and January 2015). Only 7 PLHIV (or 7% of the baseline sample) did not experience any form of food insecurity. In terms of severity of food insecurity, a high percentage (74%) of the study sample reported severe food insecurity. This percentage translates to 75 out of 101 ART patients in the study. Two percent of the study sample (or 2 patients) experienced mild food insecurity, and 17% (or 17 patients) reported moderate food insecurity. Further, the average baseline household food insecurity access scale (HFIAS) score was 14.42 (standard deviation = 7.86), which is slightly higher than the midpoint of the range of possible scores. The minimum HFIAS score was 0 and the maximum was 27.

The proportion of households that reported experiencing various food insecurity conditions at any time during the recall period varied depending on the condition. Table 6 presents the proportion of households that experienced food insecurity-related conditions and the frequency of experiencing food insecurity conditions. For instance, 83% of the sample reported that they worried that their households would not have enough food, with 37% worrying about access to food often, or more than ten times in the past four weeks. A slightly higher percentage (88%) reported not being able to eat the kind of foods they preferred, with 40% experiencing this condition more than ten times in the past four weeks. In addition, 86% of the sample reported eating a limited variety of food or eating some foods they really did not want to eat because of a lack of resources to obtain adequate food. In both conditions, 41% of the sample and their households experienced these conditions more than ten times in the past four weeks. Eighty-six percent also reported eating a smaller meal than needed because there was not

enough food. However, a slightly lower proportion of households (40%) experienced this condition more than ten times in the past four weeks. Compared with the previous food insecurity conditions, a slightly lower proportion (81%) of the sample and their households experienced eating fewer meals in a day because there was not enough food. Forty-two percent ate fewer meals in a day more than ten times in the past four weeks.

Furthermore, a lower proportion of the sample reported experiencing more severe food insecurity-related conditions. For instance, 64% of the sample experienced not having food to eat of any kind in the household; 53% reported going to sleep at night hungry because there was not enough food; and 50% experienced spending a whole day and night without eating because there was not enough food. Similarly, a smaller proportion of the sample reported experiencing these acute forms of food insecurity-related conditions more than ten times in the past four weeks. In particular, 25% of the sample and their households often did not have food to eat of any kind because of lack of resources to get food; 11% often went to sleep at night hungry because there was not enough food; and 8% often spent a whole day and night without eating anything because there was not enough food. These percentages are much smaller than the proportion of households (between 37% and 42%) that often experienced less severe forms of food insecurity (e.g., worrying that the household would not have enough food, not being able to eat the kinds of preferred foods because of a lack of resources, and eating a limited variety of foods due to a lack of resources).

Follow-up (midpoint) household food insecurity. Overall, food insecurity decreased at follow-up, or eight months after baseline. The average follow-up HFIAS score was 11.34 (SD = 6.47), or three points lower than the baseline HFIAS score of 14.43 (SD = 7.86). Comparison of the proportion of ART patients by food insecurity category between baseline and follow-up indicated a more mixed pattern. Although the percentage of food-secure ART patients decreased by 2% (from 7% at baseline to 5% at follow-up), the proportion of moderately and severely food-insecure ART patients declined. For instance, the percentage of ART patients who

reported severe food insecurity dropped from 74% at baseline to 70% at follow-up. The proportion of moderately food-insecure ART patients also went down from 17% at baseline to 14% at follow-up. On the contrary, the proportion of mildly food-insecure ART patients increased from 2% at baseline to 11% at follow-up.

Furthermore, the percentage of ART patients who reported experiencing various food insecurity conditions decreased at follow-up. Table 6 presents the proportion of households that experienced food insecurity-related conditions and the frequency of experiencing food insecurity conditions both at baseline and follow-up. Across all nine conditions, the proportion of ART patients who experienced a particular food insecurity-related condition *often* (or more than ten times during the past four weeks) decreased from baseline to follow-up. For instance, the baseline proportion of ART patients who reported worrying that their households would not have enough food was 37%. At follow-up, the proportion of ART patients who reported the same food-insecurity condition dropped to 15%, or a 22% point decrease. The biggest decrease was reported on the condition related to eating a smaller meal than needed because there was not enough food. The baseline proportion of ART patients who reported experiencing this condition often was 40%, whereas the percentage decreased to 15% at follow-up, or a percentage change of 25% from baseline to follow-up.

On the contrary, the proportion of ART patients who reported *never* experiencing a particular food-insecurity condition increased in seven of nine indicators. For instance, the percentage of ART patients who *never* ate a smaller meal than needed because there was not enough food increased by 15% - from 14% at baseline to 29% at follow-up. The proportion of ART patients who *never* spent a whole day and night without eating anything because there was not enough food increased by 25% - from 50% at baseline to 75% at follow-up. Similarly, the proportion of the sample that experienced food-insecurity conditions regardless of frequency decreased in seven of nine indicators. For instance, the percentage of ART patients who experienced eating some foods that they really did not want to eat because of a lack of resources

to obtain other types of food declined from 86% at baseline to 81% at follow-up. At baseline, 86% also reported eating a smaller meal than needed because there was not enough food. At follow-up, 71% of the sample reported eating a smaller meal than needed because there was not enough food, or a decline of 15% from baseline to follow-up.

Risk Factors for Food Insecurity among ART patients

Bivariate results. Table 4, column 3 shows results of bivariate tests examining the association between characteristics of ART patients and their household food insecurity scores. For binary or categorical variables, household food insecurity scores by group were reported. For continuous predictors, I created two categories based either on the median value of observed scores (e.g., asset indices) or information from the literature (e.g., household size based on national average). Simple regression coefficients were also presented for continuous predictors. As illustrated in Table 4, food insecurity was higher among certain groups of ART patients. Overall, patients with suboptimal adherence levels had higher food insecurity scores than patients with optimal ART adherence rates. For instance, patients with medication possession ratio (MPR) less than 95% scored nearly two points higher (15.41) on the HFIAS than patients with MPR at or above 95% (13.91). However, none of the bivariate relationships between food insecurity and ART adherence were statistically significant.

As shown in Table 4 (column 3), the following categorical variables were significantly associated with food insecurity: gender, education level, financial situation, household income, transportation asset (above or below median index value), saving frequency, health perception, and perceived distress. For instance, women were more food insecure than men. Women scored three points higher on the food insecurity scale contrasted with men. Furthermore, five of five socioeconomic indicators that were measured originally as continuous variables were significantly associated with access to food ($p < .05$). Bivariable linear regression results indicated that household size and four asset ownership measures (land, mode of transport, household possessions, and livestock) were significant predictors of household food security.

For instance, food insecurity decreased by 0.45 point for every one person increase in household size. Similarly, for every one unit increase in landownership, food insecurity decreased by 0.40 point. For the three asset variables that were measured using an index, results indicated that higher asset ownership was associated with lower food insecurity. The coefficients for the three variables differed substantially – from -0.64 for livestock ownership to -4.32 for household possessions and -5.30 for transportation-related asset. Also, compared with dummy (binary) variables and comparison of group means, all bivariate associations using the original continuous measures were statistically significant.

Multivariable results. Table 7 presents results of regression analysis of the relationship between food insecurity and characteristics of ART patients from the multiple imputation model. The second column of Table 7 shows results of Model 1 that examined the association between food insecurity and demographic characteristics of ART patients. The third column lists Model 2 results, which controlled for demographic characteristics in assessing the relationship between food insecurity and social and economic characteristics of ART patients. The fourth column shows results of Model 3 that examined the relationship between food insecurity and health characteristics, in addition to demographic and socioeconomic factors. The fifth column presents results of the final and more parsimonious model (Model 4) that was obtained after backward elimination procedure.

In Model 1, findings were consistent with the bivariate analysis results. Age was negatively associated with food insecurity ($\beta = -0.13$). Men were less likely to be food insecure compared with women ($\beta = -2.67$). Married ART patients were less likely to be food insecure compared with non-married ART patients ($\beta = -1.04$). In addition, ART patients with at least secondary education scored lower on the food insecurity scale ($\beta = -4.63$) compared with their peers who had primary education only. ART patients whose main occupation was non-farming scored lower on the food insecurity scale ($\beta = -1.30$), and were less likely to experience food insecurity compared with their peers whose main occupation was farming. ART patients from

Lumezi were more likely to experience food insecurity ($\beta = 1.26$) than ART patients from Lundazi. The relationship between head of household status and food insecurity was reversed. ART patients who were heads of households were more likely to be food insecure ($\beta = 0.95$) than their peers who were non-heads of households. However, education was the only demographic characteristic that was a significant predictor.

In Model 2, results showed three significant financial and economic predictors of food insecurity. First, ART patients who reported that their financial situation stayed the same or was better than two years ago were less likely to experience food insecurity ($\beta = -3.39$) than their peers whose financial situation deteriorated. Second, ART patients with monthly income between K51 – K500 (between US\$0.30 to US\$2.75 per day) were less likely to be food insecure ($\beta = -5.44$) compared with ART patients with monthly income of less than K21 (or <US\$0.15). ART patients with monthly income of \geq K501 (or > US\$2.75 a day) also were less likely to be food insecure ($\beta = -8.81$) compared to the reference group. However, ART patients with monthly income between K21 – K50 were more likely to be food insecure ($\beta = 0.33$) than ART patients with income between K0 – K20 per month, albeit not statistically significant. Third, ART patients who reported saving sometimes or more frequently were more likely to be food insecure ($\beta = 4.16$) than ART patients who reported not saving money. This finding suggests that PLHIV and their households may defer food consumption in order to save money and pay for expected expenses which may include HIV treatment-related costs. In addition to these three predictors, asset ownership had a positive relationship with food security. ART patients who owned more household possessions ($\beta = -1.92$), livestock ($\beta = -0.02$), and transportation assets ($\beta = -2.06$) were less likely to be food insecure than their peers with fewer assets. Similarly, ART patients who reported owing money were more likely to be food insecure ($\beta = 3.40$) compared with their peers who did not owe money. However, landownership was negatively associated with food insecurity ($\beta = 0.04$). Household size was negatively associated with food insecurity ($\beta = -0.23$). However, none of these associations were statistically significant. In addition, none of the

demographic indicators in Model 1 were statistically significant after adding the social and economic variables in Model 2.

In Model 3, results showed that mental health status of ART patients was an important factor for food security. For instance, PLHIV who coped better with stress were less likely to experience food insecurity. For every one point increase in the coping factor of the perceived stress scale, food insecurity decreased by 0.53 point. Similarly, PLHIV who experienced mental distress frequently were more likely to report food insecurity. For every one point increase in the distress factor of the perceived stress scale, food insecurity increased by 0.59 point. ART patients who rated their health status as good, very good or excellent scored 1.76 points lower on the food insecurity scale compared with their peers with fair or poor self-perceived health status. Both perceived stress factors were statistically significant predictors of food insecurity ($p < .05$), whereas the relationship between self-perceived health status and food insecurity was not significant. The other health factor, ART treatment duration, was not a significant predictor of food insecurity. In addition, ownership of household possessions became a significant and positive predictor of food security after adding the health characteristics in Model 3. For every one unit increase in the household possessions index, food insecurity decreased by 3.31 points.

The final model or Model 4 included nine predictors of food insecurity among PLHIV who are receiving ART. Six predictors were financial and economic-related factors, two were health characteristics, and one was a demographic variable. For instance, ART patients with monthly income between K51 – K500 scored 5.13 points lower on the food insecurity scale compared with ART patients with monthly income between K0 – K20. Asset ownership remained a positive predictor of food security, and ART patients who owned more assets were less likely to be food insecure. For every one unit increase in the household possession index, food insecurity decreased by 2.74 points. Similarly, for every one unit increase in the transportation asset index, food insecurity decreased by 2.81 points. On the contrary, ART patients who reported owing money were more likely to be food insecure. ART patients with

monetary debts scored 3.16 points higher on the food insecurity scale compared with their peers without monetary debts. With the exception of transportation asset, all these associations were statistically significant ($p < .05$). The relationship between ownership of transportation asset and food insecurity approached statistical significance ($p < .10$). The associations between household size, financial situation, and having a monthly income of at least K501 and food insecurity also demonstrated statistical significance ($p < .10$). Having a financial situation that stayed the same or was better than two years ago remained a positive predictor of food insecurity ($\beta = -2.84$), as well as having a monthly income of at least K501 ($\beta = -5.24$). With health factors, PLHIV who coped better with stress remained less likely to experience food insecurity. For every one point increase on the coping factor of the perceived stress scale, food insecurity decreased by 0.51 point. In contrast, ART patients who experienced frequent mental distress were more likely to be food insecure. For every one point increase on the distress factor of the perceived stress scale, food insecurity increased by 0.59 point. Both relationships remained statistically significant ($p < .05$). Finally, living in Lumezi was associated with higher risk of food insecurity. ART patients from Lumezi scored 1.79 points higher on the food insecurity scale than Lundazi ART patients. However, this relationship was not statistically significant ($p < .10$). In sum, in this final and more parsimonious model, five variables were statistically significant predictors of food insecurity ($p < .05$). As expected, all but one variable in Model 4 showed consistency (i.e., numerical stability and same direction of relationship) across models. The relationship between ART patients' residence and food insecurity was consistent in Models 1, 3 and 4.

R² for multiple imputation models. Using the *mibeta* command in Stata, I obtained the R^2 and adjusted R^2 values for all models. Simulation results conducted by Harel (2009) suggest that R^2 estimates from multiple imputed data tend to be biased upwards while adjusted R^2 estimates tend to be biased downwards. Because of these biases, I reported both R^2 and adjusted R^2 in Table 7. The general trend was higher R^2 and adjusted R^2 values as more

predictor variables were included in the models. The final model's R^2 value was 0.59, which was 0.02 point lower than Model 3's R^2 value but with 11 fewer variables in the model. On the other hand, adjusted R^2 values were higher in Model 4 (0.53) than Model 3 (0.49). When using R^2 , results showed that 59% of the variability of food insecurity in this sample of ART patients in Lundazi District was explained by the predictors included in the final model. Similarly, based on adjusted R^2 , 53% of the variability of food insecurity was explained by the final model. In sum, the final and more parsimonious Model 4 fit the data best compared with the first three models.

Relationship between Food Insecurity and ART Adherence

Bivariate results. Table 4, Columns 4 to 7 show results of bivariate tests examining the association between characteristics of ART patients (including food insecurity) and their optimal ART adherence levels. Columns 4 and 5 present results using the baseline 30-day VAS, whereas columns 6 and 7 display findings using the baseline MPR data. For binary or categorical variables, columns 4 and 6 list the proportion of optimally adherent ART patients in the study, whereas columns 5 and 7 present the proportion of ART patients with suboptimal adherence level. For VAS, suboptimal adherence level referred to less than 100% of prescribed doses taken. For MPR, suboptimal adherence level meant less than 95% of prescribed doses taken. Consistent with research question 2, treatment adherence rates by group were reported for binary or categorical variables. For continuous predictors, I created two categories based either on the median value of observed scores (e.g., asset indices) or information from the literature (e.g., household size based on national average). Odds ratio from simple logistic regression was also presented for continuous predictors.

Food insecurity and visual analog scale. As illustrated in Table 4, a higher proportion (86%) of food secure ART patients was optimally adherent contrasted with moderately (71%) or severely (74%) food-insecure patients at baseline. With the exception of mildly food insecure patients (of which there were only two), food-insecure patients (29% for moderately and 26% for severely food insecure) were more likely to report suboptimal ART

adherence contrasted with food-secure patients (14%). Similarly, simple logistic regression result indicated that baseline food insecurity was associated with suboptimal ART adherence. For every one point increase in the household food insecurity access scale, the likelihood of achieving optimal ART adherence decreased by 1% (95% CI 0.93, 1.05). However, none of the bivariate relationships between food insecurity and self-report ART adherence (using a 30-day visual analog scale) was statistically significant ($p > .05$).

Food insecurity and medication possession ratio. Consistent with the VAS results, a higher proportion (86%) of food secure patients was optimally adherent compared with moderately (69%) or severely (65%) food insecure patients at baseline (Table 4, columns 6 and 7). With the exception of mildly food insecure patients (of which there were only two), food-insecure ART patients were more likely to report suboptimal ART adherence contrasted with food-secure patients. Thirty-one percent of moderately food insecure and 35% of severely food insecure ART patients were not optimally adherent based on their baseline MPR (i.e., < 95%) contrasted with 14% of food secure ART patients. Similarly, simple logistic regression result indicated that baseline food insecurity was associated with suboptimal ART adherence. For every one point increase in the household food insecurity access scale, the likelihood of achieving optimal ART adherence decreased by 2% (95% CI 0.93, 1.03). However, none of the bivariate relationships between food insecurity and medication possession ratio was statistically significant ($p > .05$).

Comparison of adherence rates by patient characteristics indicated that adherence levels varied by type of adherence measure. For instance, the proportion of severely food-insecure ART patients with optimal adherence level was 74% based on VAS and 65% based on MPR. Similarly, the proportion of adherent ART patients with at least secondary education was 70% based on the VAS and 59% based on MPR. Also, the proportion of Lumezi patients with optimal adherence was 72% based on VAS and 57% based on MPR. The biggest gap (i.e., 20 percentage points) in reporting by group was found in ART patients who reported owing money. Based on

VAS, 78% of ART patients with debts reported optimal adherence contrasted with 58% of ART patients when using MPR. Consistent with the treatment adherence levels in the overall sample, bivariate results suggest that higher optimal adherence levels were more likely to be reported when using VAS than MPR. In sum, the self-reported VAS might be more susceptible to overreporting than MPR, which was obtained using pharmacy records. As stated earlier, recall and social desirability of response issues might have contributed to overreporting in the baseline VAS contrasted with MPR, which was a more objective, albeit proxy, measure of ART adherence.

Multivariable results. Table 8 displays multivariable logistic regression results on the relationship between baseline ART adherence and food insecurity using multiply imputed data. Columns 2 and 3 of Table 8 outline the findings on the relationship between an interval-level food security variable and optimal ART adherence measured using a 30-day visual analog scale. For this relationship, five covariates were included in the model. These covariates were type of occupation, residence, ownership of transport-related asset, livestock ownership, and health perception. As stated in Chapter 3, these covariates were retained based on results of the purposeful variable selection.

Columns 4 to 9 present results on the relationship between food insecurity and baseline ART adherence measured using the medication possession ratio obtained from pharmacy records. I examined this relationship based on three definitions of optimal adherence. The first and primary definition was based on $\geq 95\%$ threshold, i.e., the patient took 95% or more of prescribed doses. These results were presented in Columns 4 and 5. The second definition was based on $\geq 90\%$ threshold, and these findings were listed in Columns 6 and 7. The third and final definition was based on $\geq 80\%$ threshold, and results were presented in Columns 8 and 9. For the relationship between food insecurity and MPR, ten covariates were included in the model. These covariates were education level, financial situation, household income, ownership of transport-related assets, debt, perceived stress (two dimensions – inefficacy and helplessness), HIV treatment duration, and access to health facility (distance to health facility and travel time

to health facility). Consistent with VAS, these covariates were included in the final models based on results of the purposeful variable selection described in Chapter 3. Appendix D shows results of the covariate selection process for both VAS and MPR.

Food insecurity and visual analog scale. Multivariable results indicated that food insecurity had no effect on ART adherence measured using a 30-day visual analog scale (Adjusted Odds Ratio [AOR] = 1.00, 95% CI 0.93 – 1.07). Although the key explanatory variable of interest demonstrated no relationship with ART adherence, three covariates were statistically significant predictors of ART adherence ($p < .05$) and one covariate demonstrated statistical trend ($p < .10$). The statistically significant covariates included residence, ownership of transport-related asset, and health perception. The relationship between livestock ownership and optimal ART adherence approached statistical significance. First, Lumezi ART patients were less likely to adhere optimally to ART by 80% contrasted with Lundazi patients. Second, ART patients who owned more transport-related assets were less likely to achieve optimal ART adherence contrasted with ART patients with fewer transport-related assets. In particular, for every one unit increase in the transportation asset index, the likelihood of achieving optimal ART adherence decreased by 89%. Third, ART patients with better self-perceived health also were more likely to achieve optimal ART adherence compared with ART patients with poorer self-rating of their health. For every one level increase in health perception (e.g., from fair to good), the probability of achieving optimal ART adherence during the past 30 days increased by 105%. Fourth, ART patients who owned more livestock were more likely to adhere optimally to their HIV treatment medications than ART patients who owned fewer livestock. For every one unit increase in the livestock ownership index, the likelihood of adhering to ART optimally increased by 20%.

Food insecurity and medication possession ratio. Overall, results of the relationship between food insecurity and ART adherence measured using medication possession ratio were consistent across the three thresholds – $\geq 95\%$, $\geq 90\%$ and $\geq 80\%$ (see Table 8). Unlike

the VAS results, food insecurity was associated with higher odds of suboptimal adherence regardless of the adherence threshold. For instance, every one point increase in the household food insecurity access scale decreased the likelihood of optimal ART adherence (defined at the $\geq 95\%$ threshold) by 7% (AOR 0.93, 95% CI 0.85 – 1.03). Similarly, when optimal adherence was defined at the $\geq 90\%$ level, every one point increase in food insecurity decreased the likelihood of optimal adherence by 7% (AOR 0.93, 95% CI 0.84 – 1.03). Food insecurity also was negatively associated with optimal ART adherence at the $\geq 80\%$ level. For every one point increase in food insecurity, the probability of achieving optimal adherence (defined as $\geq 80\%$ of prescribed medication taken) decreased by 5% (AOR 0.95, 95% CI 0.85 – 1.05). Although the adjusted relationships between food insecurity and ART adherence as measured by MPR were not statistically significant ($p > .05$, two-tailed test), the consistent direction of the relationship across the three adherence thresholds support prior studies that found an inverse relationship between food insecurity and optimal ART adherence. In addition, the narrow confidence intervals across all measures indicate a higher precision of the odds ratio despite the relatively small sample size of the study. Finally, I examined the results using a one-tailed test given that prior research has shown negative association between food insecurity and ART adherence. When a one-tailed test was applied, the relationships between food insecurity and ART adherence (measured by MPR) at the $\geq 95\%$ and $\geq 90\%$ thresholds demonstrated statistical trend ($p < .10$).

In terms of covariates, results were consistent. As presented in Table 8, the direction of associations was identical for each covariate across all models and adherence thresholds. For most covariates, odds ratios were similar across all three MPR models. Differences in odds ratios did not exceed 0.50 point. Differences in level of statistical significance were minimal. Among the ten covariates, household income, perceived stress, and travel time to health facility had positive associations with optimal adherence. On the contrary, ownership of transport-related asset, HIV treatment duration, and distance to health facility had negative associations

with optimal ART adherence. With the categorical predictors, having more education, better financial outlook, and having debts decreased the likelihood of achieving optimal ART adherence. None of the covariates were statistically significant across all three MPR models. Travel time to health facility was significantly associated with optimal ART adherence at the $\geq 95\%$ threshold.

Sensitivity results. As mentioned in Chapter 3, I created five categorical food insecurity variables based on the continuous-level food insecurity scores and categorical prevalence distribution. I conducted multivariable logistic regressions controlling for the same sets of covariates (for VAS and MPR) as listed in Table 8, but with a different specification of food insecurity. The purpose of these analyses was to check robustness of the association between food insecurity and ART adherence, as well as to assess whether results were sensitive to variation of model specification (in particular, categorization of the food insecurity variable). Table 9 presents results of the sensitivity analyses that examined associations between ART adherence and alternative specifications of food insecurity. Columns 2 and 3 of Table 9 show results based on the 30-day visual analog scale. Columns 4 to 9 illustrate results based on MPR and three adherence thresholds – $\geq 95\%$ (Columns 4 and 5), $\geq 90\%$ (Columns 6 and 7), and $\geq 80\%$ (Columns 8 and 9). All results were estimated based on multiply imputed data with 20 imputations.

Overall, results were consistent with the negative association between an interval-level food insecurity variable and ART adherence. Based on both VAS and MPR as measures of adherence, higher levels of food insecurity reduced the probability of achieving optimal ART adherence. First, a comparison of results using VAS indicated that food insecurity was associated with lower odds of optimal treatment adherence. Although these results were not statistically significant, they contradict the findings of a lack of association between an interval-level food insecurity variable and optimal ART adherence based on a 30-day VAS (AOR = 1.00). Second, a comparison of MPR results indicated that food insecurity was associated with lower

odds of optimal treatment adherence. Consistent with VAS results, higher levels of food insecurity reduced the probability of optimal ART adherence as measured by MPR and defined by three different treatment adherence thresholds. The associations between binary food insecurity variables and ART adherence were consistent across the three MPR thresholds - $\geq 95\%$, $\geq 90\%$, and $\geq 80\%$. Although the directions of relationship were identical, adjusted odds ratios differed based on the adherence level. In general, adjusted odds ratios were smaller in the $\geq 95\%$ threshold compared with the $\geq 90\%$ and $\geq 80\%$ levels. These findings were expected because as odds ratio increases, the probability of not having the event (in this case suboptimal adherence) decreases, which is consistent with higher likelihood of achieving optimal adherence as the threshold is reduced from $\geq 95\%$ to $\geq 90\%$ to $\geq 80\%$. Although the probability of not experiencing the event of interest decreased as adherence threshold was lowered, food insecure ART patients remained at higher risk of suboptimal treatment adherence compared with their food-secure peers regardless of the optimal threshold.

These additional analyses also demonstrated that severe forms of food insecurity further increased risk of suboptimal treatment adherence. For instance, ART patients who were experiencing more frequent and severe forms of food insecurity were at even higher risk of suboptimal adherence compared with ART patients who were either food secure or mildly food insecure. Although the observed relationships were not statistically significant, the consistent pattern across treatment adherence thresholds and severity of food insecurity suggests that as ART patients become more food insecure they also take their medications less frequently and increasingly missed their doses as prescribed. The remaining categorical definitions of food insecurity (i.e., severe food insecurity versus non-severe food insecurity, food insecurity scores at or above the median or mean score vs. food insecurity below the sample's average) also demonstrated an inverse relationship between food insecurity and optimal ART adherence.

In summary, results of the sensitivity analyses support the earlier findings that food insecurity is negatively associated with optimal ART adherence. Regardless of how the food

insecurity variable was operationalized (i.e., continuous, binary, or multi-categorical), the direction of the relationship remained the same across various model specifications, adherence measures, and optimal adherence thresholds. Although the results were not statistically significant, the consistent pattern of negative association between food insecurity and optimal ART adherence suggests that the observed inverse relationship is robust and not sensitive to variation of model specification, including operationalization of the key explanatory variable, type of adherence measures and optimal treatment threshold.

Impacts of Health and Wealth

Comparison of baseline and follow-up outcomes. Overall, the study sample reported better outcomes eight months after baseline and two months after delivery of intervention training. Results were based on multiply imputed datasets. For instance, food insecurity score decreased from 14.43 at baseline to 11.84 at follow-up. Although both treatment and control groups reported lower food insecurity scores at follow-up, treatment group reduced their food insecurity at a much higher rate than control group. For instance, mean food insecurity score in the treatment group decreased from 15.32 at baseline to 10.21 at follow-up, or a change score of -5.10 points. On the contrary, mean food insecurity score in the control group declined from 13.55 at baseline to 13.44 at follow-up, or a change of -0.11. Although the control group was less food insecure at baseline, the treatment group reported lower food insecurity at follow-up compared with the control group.

The study sample also reported better ART adherence. The overall proportion of ART patients who reported optimal adherence (based on a 30-day VAS) increased from 73% at baseline to 81% at follow-up. Treatment and control groups had identical follow-up optimal adherence rates at 81%. However, optimal ART adherence increased at a higher rate among treatment participants than control participants. For instance, the proportion of optimally adherent patients in the treatment group increased from 68% at baseline to 81% at follow-up.

On the contrary, the proportion of optimally adherent patients in the control group increased from 78% at baseline to 81% at follow-up.

Bivariate results. Bivariate results indicated that participation in *Health & Wealth* positively contributed to better outcomes. Table 10 presents results of the differences in outcomes before and after adjustment for baseline values. Unadjusted mean difference showed that treatment participants had lower follow-up food insecurity score than control group. ART patients in Lumezi (treatment group) scored 3.23 points lower on HFIAS contrasted with ART patients in Lundazi (control group). When results were adjusted for baseline food insecurity, treatment group remained less food insecure than control group. Treatment group scored 3.77 points lower on HFIAS than control group. Although baseline food insecurity values were not statistically different between groups, follow-up food insecurity scores (both unadjusted and adjusted for baseline) were statistically significant between treatment and control patients ($p < .05$).

Treatment participants also performed better on ART adherence contrasted with control participants. Based on unadjusted results, treatment participants were 3% more likely to achieve optimal ART adherence contrasted with control participants. Similarly, when results were adjusted for baseline ART adherence, treatment participants were 12% more likely to report optimal adherence (based on a 30-day VAS) compared with control participants. Although results were not statistically significant, participation in *Health & Wealth* contributed to positive increase in optimal ART adherence among treatment participants.

Multivariable results (Regression adjustment). Table 10 presents differences in outcomes before and after multivariable adjustment. In addition, Table 11 shows complete multivariable results after covariate adjustment. Multivariate results were consistent with bivariate findings. Overall, *Health & Wealth* had positive effects on food security and optimal ART adherence. For instance, after controlling for potential confounders including baseline food insecurity, treatment group scored 5.76 points lower on HFIAS compared with control

participants. This coefficient was two points lower than the bivariate findings. The effect of *Health & Wealth* on food insecurity, after adjusting for covariates of the outcome, was statistically significant ($p < .05$, 95% CI [9.78, -1.75]). Similarly, *Health & Wealth* had a positive effect on optimal ART adherence. The treatment group was 19% more likely to report optimal ART adherence than the control group, after adjusting for covariates of treatment adherence. This odds ratio was slightly higher than the odds ratio based on adjusted baseline ART adherence. Consistent with bivariate results, the effect on optimal ART adherence was not statistically significant ($p > .05$, 95% CI [0.20, 7.04]).

The multivariable regression models also allowed examination of the association of baseline characteristics and key outcomes at follow-up. Consistent with baseline results, household size, financial status and asset ownership were inversely associated with food insecurity. For instance, ART patients with better financial situation at baseline were less food insecure at follow-up ($\beta = -5.11$) than their peers with worse financial situation. Similarly, more assets owned at baseline were associated with less food insecurity eight months later. Baseline food insecurity was also positively associated with food insecurity eight months after baseline ($\beta = 0.08$). On the contrary, having debts at baseline was inversely associated with food insecurity, whereas higher income at baseline was positively associated with food insecurity. However, these relationships between baseline covariates and follow-up food insecurity were not statistically significant. Only one baseline covariate was a statistically significant predictor of food insecurity at follow-up – perceived coping. Although the relationship was statistically significant, the direction was reversed at follow-up. For every one unit increase in the baseline coping dimension of perceived stress, food insecurity worsened by 0.64 point. Furthermore, associations between baseline covariates and follow-up optimal ART adherence were generally consistent with research question 3 results. The effect of asset ownership remained mixed. Better self-perceived health at baseline remained a positive predictor of optimal adherence. Similarly, being optimally adherent to ART at baseline was associated with higher likelihood of

being optimally adherent eight months after baseline. Unlike baseline (research question 3) findings, baseline food insecurity was marginally associated with optimal ART adherence (AOR = 1.01). Also, the direction of association between occupation type and ART adherence was reversed at follow-up. The other association that changed direction was the effect of geographic residence or treatment assignment. At baseline, Lumezi patients (treatment group) were less likely to report optimal ART adherence compared with Lundazi patients (control group, AOR = 0.20, $p < .05$). As stated earlier, eight months after baseline, Lumezi patients became more likely to report optimal ART adherence compared with Lundazi patients (AOR = 1.19). However, none of these associations were statistically significant.

Treatment effect model: Food security.²² The treatment effect models adjusted for heterogeneity of *Health & Wealth* participation by taking into consideration covariates hypothesized to affect selection bias. Table 10 presents the estimated differences on food security between treatment and control groups before and after adjustments for sample selection. In addition, Table 12 lists the complete results (regression and selection equations) after adjustment of sample selection using multiply imputed datasets.

First, selection bias appeared to be a problem because a number of variables included in the selection equation were statistically significant. Treatment and control groups were significantly different on the following characteristics: ownership of transportation assets and household possessions, ART adherence and ART treatment duration. ART patients who reported owning more transport-related assets and household possessions at baseline were less likely than ART patients with fewer assets to receive *Health & Wealth* treatment. ART patients with optimal medication adherence level were less likely than ART patients with suboptimal adherence to receive *Health & Wealth* treatment. ART patients who had been in treatment for

²² In Stata, application of the treatment effect model after multiple imputations of missing data is currently not available for binary outcome variables. For this reason, the effect of *Health & Wealth* on optimal ART adherence was obtained using logistic regression that took into account potential confounders.

longer than 19 months were more likely than their counterparts who had been in treatment for 19 months or less to receive *Health & Wealth* treatment.

Second, based on the regression equation that controlled for covariates of outcome variables, participation in *Health & Wealth* had positive effect on key outcomes. Results showed that *Health & Wealth* produced positive changes in ART patients' food security. Treatment participants were less likely to be food insecure eight months after baseline compared with control participants. Treatment participants scored 5.65 points lower on HFIAS than control participants. This effect of *Health & Wealth* was statistically significant ($p < .05$). In addition, the observed relationships of baseline covariates and follow-up outcome were consistent with results based on multivariable models that controlled for potential confounders as presented in Table 11.

Third, comparison of treatment effect model results based on two different procedures (maximum likelihood and two-step) showed consistent results. Table 10 displays results of treatment effect model using maximum likelihood (ML) estimator and two-step procedure. Treatment effect results using either ML or two-step showed that *Health & Wealth* produced positive changes in ART patients' food security. The treatment group scored 5.65 points lower on HFIAS based on ML estimates and 5.49 points lower based on two-step estimates compared with the control group. Both results were statistically significant at the .05 level.

Sensitivity analysis: Comparison of different multiple imputation models. To determine whether results were sensitive to the number of imputations (m), I created three additional multiple imputation models with 5, 50 and 100 multiply imputed datasets. Table 13 compares treatment effect outcomes before and after adjustment of sample selection based on number of multiply imputed datasets. The upper portion of Table 13 display results based on 20 multiply imputed datasets (primary analysis model), the middle portion list results based on 5 and 50 multiply imputed datasets (sensitivity analysis model), and the bottom portion shows results based on 100 multiply imputed datasets (sensitivity analysis model). Overall, results

were consistent across different number of imputations. The directions of treatment effects were identical. Across all models, *Health & Wealth* had a positive effect on food insecurity and ART adherence. Mean differences and odds ratio for each outcome were similar. In addition, levels of statistical significance were generally consistent across different numbers of multiply imputed datasets.

In all models, results showed that *Health & Wealth* reduced food insecurity at follow-up. Results based on five multiply imputed datasets had higher point estimates than models with 20, 50 and 100 multiply imputed datasets. For instance, baseline-adjusted (food insecurity) mean difference based on five multiply imputed datasets was -4.41 contrasted with -3.77 ($m = 20$), -3.90 ($m = 100$), and -3.91 ($m = 50$). Regression-adjusted mean difference was highest for $m = 5$ (-6.59), followed by $m = 50$ (-6.07), and $m = 20$ and $m = 100$ (-5.76). The trend was identical for adjusted mean differences based on sample selection using ML and two-step procedures – that is, mean difference was the highest for $m = 5$, followed by $m = 50$, $m = 100$ and $m = 20$. Although all results were statistically significant, results based on five multiply imputed datasets were more likely to be significant at the 0.01 level or lower than at the 0.05 level. In other words, results based on five multiply imputed datasets were more highly significant than results based on larger number of imputed datasets.

For optimal ART adherence, results were also generally consistent across primary and sensitivity models. Overall, *Health & Wealth* had a positive, albeit not statistically significant, effect on optimal ART adherence. Unadjusted odds ratio in models with 20 and 100 datasets indicated that treated participants were slightly more likely to achieve optimal adherence (between 1% and 3%) than non-treated participants. However, unadjusted odds ratio in $m = 5$ showed no program effect on optimal ART adherence, whereas in $m = 50$, *Health & Wealth* had a negative, albeit minimal, effect (AOR = 0.99). Results were more consistent when covariates were added. In all baseline-adjusted and multivariable regression models, treatment group was more likely to report optimal ART adherence than control group. Adjusted odds ratios were

slightly higher in models with smaller number of datasets ($m = 5$ and 20) contrasted with models with larger number of datasets ($m = 50$ and 100). For instance, multivariable adjusted odds ratios were 1.12 and 1.19 for $m = 5$ and $m = 20$, respectively compared with 1.01 and 1.05 for $m = 50$ and $m = 100$.

In summary, evidence indicates that results were not sensitive to the number of imputations. Results based on 20 multiply imputed datasets did not change substantially and significantly when the number of multiply imputed datasets were decreased to five or increased to 50 or 100 . Direction of associations, significance levels and effect sizes (i.e., coefficients and odds ratios) were consistent and comparable across models and number of imputations. Although results were consistent, models with larger number of multiply imputed datasets (e.g., 20 , 50 and 100) had more comparable findings than the model with fewer number of multiply imputed datasets (e.g., 5).

CHAPTER 5: DISCUSSION, IMPLICATIONS, LIMITATIONS, and CONCLUSIONS

Discussion

Prevalence of Food Insecurity

The first research question of this dissertation assessed the prevalence of food insecurity among rural ART patients in Zambia. Prevalence of food insecurity was examined at two time points – baseline (conducted between December 2014 and January 2015) and follow-up (collected in September 2015). Evidence indicates that food insecurity, particularly inadequate access to food, remains high among ART patients in Lundazi District. At baseline, 93% of respondents were considered food insecure. At follow-up, the percentage of food-insecure respondents increased slightly to 95%. Among ART patients who were food insecure, most were severely food insecure – 74% at baseline and 70% at follow-up, followed by moderately food insecure (17% at baseline and 14% at follow-up), and mildly food insecure (2% at baseline and 11% at follow-up). The high prevalence of food insecurity – both at baseline and follow-up – is consistent with prior studies in resource-limited and resourced adequate settings (e.g., Normén et al., 2005; Musumari et al., 2014; Tsai et al., 2011) that have found a large proportion of food-insecure PLHIV, regardless of treatment status.

Prevalence differs between Lumezi and Lundazi. In this sample of ART patients, food insecurity differs based on geographic residence. At baseline, ART patients from Lumezi (treatment site) reported higher rate of food insecurity compared with ART patients from Lundazi (control site). The two sites also differ on the prevalence categories of food insecurity, with Lumezi having substantially more severely food-insecure ART patients. In Lumezi, 92% of ART patients were severely food insecure at baseline compared with 57% of Lundazi ART patients. Although follow-up food insecurity remained high, the prevalence of severe food

insecurity in Lumezi decreased from 92% at baseline to 74% at follow-up. On the contrary, the prevalence of severe food insecurity among ART patients in Lundazi increased from 57% at baseline to 66% at follow-up. The substantial decline, from baseline to follow-up, in the proportion of severely food insecure ART patients in Lumezi (treatment site) compared with Lundazi (comparison site) indicates a positive effect of *Health & Wealth* on food security, particularly reduction in severe food insecurity.

The higher prevalence of (baseline) food insecurity, including severe food insecurity, among Lumezi ART patients compared with Lundazi ART patients may not be surprising. Examination of baseline socioeconomic qualities of ART patients based on their geographic residence reveals that Lumezi residents are more likely to possess characteristics that increase their risk of food insecurity. Lumezi patients had less income contrasted with Lundazi patients. For instance, 94% of Lumezi residents had a household income of less than K50 per month, or less than \$0.30 per day, compared with 47% of Lundazi residents. None of Lumezi residents earned more than \$2.75 per day contrasted with 29% of Lundazi residents who earn more than \$2.75 per day (or more than K501 per month). In addition to being income-poor, Lumezi ART patients owned fewer assets than their counterparts in Lundazi. On average, Lumezi patients owned fewer modes of transport, livestock, and household possessions than Lundazi patients. A higher proportion of Lumezi patients (64%) did not save compared with Lundazi patients (8%). On average, Lumezi residents owned fewer acres of land (3.2) than Lundazi residents (4.39). Lumezi residents were also more likely to report worse financial situation than Lundazi residents.

The poorer socioeconomic characteristics of Lumezi ART patients and their households can be due to the level of economic opportunities available within each community. Compared with Lundazi, Lumezi's economy is less diversified. Although the local economy in both communities is dominated by agriculture and farming, trading and non-farming activities are more robust in Lundazi than Lumezi because Lundazi is the center or "county seat" of Lundazi

District. A more diverse local economy offers residents more livelihood options beyond subsistence and small-scale farming. These various livelihood options allow households to broaden their sources of income outside (and in some cases, away from) farming, which in this part of Zambia remains vulnerable to natural occurrences such as drought. The study sample's occupation type reinforces the notion of less economic opportunities (beyond farming) in Lumezi. All but one of the 50 Lumezi ART patients was a farmer or earned income from farming-related activities. In Lundazi, 47% of ART patients had a primary occupation that was not farming-based. These other types of occupation included trading, professional/managerial and service. The predominance of small-scale and subsistence farming as the primary occupation of Lumezi ART patients may explain why Lumezi residents in this study have lower socioeconomic status (that is, less income, consumption and assets) than Lundazi ART patients.

Economically Poor Households and Food Insecurity

The second research question of this dissertation examined the predictors of food insecurity in this sample of rural ART patients in Zambia. Although prior research has investigated the determinants of food security among PLHIV in SSA, fewer studies have explored the facilitators and barriers to food security among rural PLHIV on ART. Identification of “malleable” protective and risk factors can be useful to inform and guide development of food security interventions for ART patients and their households in rural communities in Zambia and elsewhere in SSA.

In this sample of rural ART patients in Zambia, results support the hypothesis that (baseline) food insecurity is a problem of low income and lack of economic security in the household. Bivariate and multivariate findings indicate that earning less income, owning fewer assets, owing money, and having poor financial situation increase the risk of food insecurity. In the final multivariable model, household income, asset ownership and debt remained statistically significant predictors of food security. Higher income (at least a daily income of K51 or \$0.30) and ownership of more household possessions reduced food insecurity. On the

contrary, owing money increased food insecurity. A better financial situation and owning more transport-related assets also reduced food insecurity. In the final multivariable model, these latter two relationships demonstrated statistical significance. Sensitivity analysis results confirm that inadequate access to food is predicted by the same set of household economic variables (i.e., income, financial status, assets and debts). Furthermore, nine predictors (including five household economic variables) accounted for more than 50% of the variation in baseline food insecurity. The parsimonious model with nine predictors illustrates the importance of household economic characteristics in predicting which ART patients are more likely to experience food insecurity.

Food insecurity among ART patients and their households in this study appears strongly to be a problem of poor financial and economic situation characterized by low income and asset ownership, as well as accumulation of debts. Obviously, less income deprives ART patients and their households of financial resources that they can use to buy food or purchase raw materials that can be used to produce food. Owning fewer assets, including non-income generating assets, may deny ART patients and their households of additional sources of income that can be utilized to meet food consumption and other needs. Owing money increases the risk of food insecurity as households are obligated to pay back money owed to creditors, which in turn, diminishes the amount of financial resources that households can use to buy or produce food.

In addition, for households affected by HIV, their household expenditures tend to be higher because of treatment-related costs associated with managing HIV. Higher household expenses further depress available financial resources that ART patients and their families can use to meet their basic needs including food. Ability to satisfy all household needs can be challenging when resources are limited and low. In some cases low-income HIV-afflicted households might be forced to choose between putting food on the table and paying for ancillary treatment costs for HIV-positive household members. In many instances, low-income households might be compelled to skip food and instead pay for HIV treatment costs especially

if the person who requires medication is the head of household or the primary breadwinner. Some households may believe that ensuring that the primary breadwinner gets the necessary treatment and is relatively healthy is a better option because then the primary breadwinner can continue earning without interruption and, in the long-term, provide some material security for the entire household.

Overall, study findings are identical with prior research in SSA that found household economic indicators (such as income, assets, living conditions and employment) to be strong correlates of food security among PLHIV (e.g., Bukusuba et al., 2007; McCoy et al., 2014; Tsai et al., 2011). The strong association between household economic indicators and food insecurity among PLHIV and their households is also consistent with research in the general population in SSA. This body of research reveals that indicators of poverty and low socioeconomic status contribute to higher risk of food insecurity in the general population (e.g., Leyna et al., 2007; Nagata et al., 2015; Singh et al., 2016). However, food insecurity among PLHIV differs from the general population because of the cumulative negative effects of HIV treatment and healthcare-related costs on household budgets and economic resources. Unlike in populations without chronic health conditions, food insecurity among low-income ART patients is exacerbated by healthcare expenses needed to manage HIV. In other words, the intersection of poverty and HIV heightens the risk of PLHIV and their households to food insecurity. Higher vulnerability of HIV-afflicted households to poverty and food insecurity suggests importance of programmatic interventions to reduce risks. Study results highlight the role of economic factors as determinants of food security. Improving household economic security is an appropriate intervention for poor PLHIV in resource-limited settings because such strategy may increase income to buy food and pay for health care-related costs. One motivation behind *Health & Wealth* is to provide ART patients with income-generating assets to lower food insecurity and improve their overall wellbeing. The effects of *Health & Wealth* on food insecurity (and ART adherence) are discussed in the impact results section of this chapter.

Food insecurity beyond economic vulnerability. Although household economic factors are important determinants of food insecurity, other important characteristics increase or decrease PLHIV's likelihood of not having adequate access to food. In the bivariate analysis, women were more food insecure than men. This finding is consistent with prior research in SSA that found women, regardless of HIV status, are at a higher risk of food insecurity compared with men (Belachew et al., 2012; Katapa, 2006; McCoy et al., 2014; Tiyou et al., 2012). Within-household bias against women increases their risk of food insecurity as women (including young girls) are not generally prioritized in the allocation of food (Haddad, Peña, Nishida, Quisumbing, & Slack, 1996; Hadley, Lindstrom, Tessema, & Belachew, 2008; Messer, 1997). In addition, women tend to have limited control over income-generating activities (Gibbs et al., 2012; McCoy et al., 2013), and cash income is viewed to be a male domain in many communities in SSA (Gladwin et al., 2001). Obviously, women's inability to control or earn income means lack or limited financial resources to buy or produce food.

In addition to gender, low education level heightens risk of food insecurity. In this sample of rural ART patients, those with primary education were more food insecure compared with those who attended secondary education or higher. In SSA, education influences the ability to earn income and diversify income sources by providing tangible skills and facilitating attitude changes that can be used to create or take advantage of livelihood opportunities (Smith et al., 2001). Individuals with higher education level because of their skills maybe more likely to earn income from various livelihood activities or adopt technology that can contribute to better food production. In turn, higher income and better agricultural yields reduce risk of food insecurity. Although mean food insecurity scores differed by gender and education level, the significant differences disappeared in multivariable analysis.

Household size was negatively (and minimally) associated with food insecurity. In this study, larger households were less food insecure. This finding may seem counterintuitive. However, larger households may comprise other working-age members who can earn additional

income and provide adequate food for all household members. The presence of other income-earning household members in an HIV-afflicted household is essential particularly when the HIV-positive household member, who may or may not be the primary income-earner, is sick and cannot work. Therefore, the income from other household members becomes an important buffer against economic shocks due to HIV/AIDS. In addition, larger household size may not necessarily worsen food insecurity if the household dependency ratio (i.e., number of non-working members versus working members) is low. Although household dependency ratio was not measured in this study, it is possible that, on average, households in the study have low dependency ratio. This low dependency ratio may also explain why household size is inversely related with food insecurity in this study.

Finally, in the multivariable analysis, perceived stress was a significant predictor of food insecurity. Higher perceived coping lessened food insecurity. Higher perceived distress heightened food insecurity. In general, prior research shows stress as an adverse effect of food insecurity among PLHIV (Addo et al., 2011; Garcia et al., 2013) and the general population (Hadley, Stevenson, Tadesse, & Belachew, 2012; Nanama & Frongillo, 2012) in SSA. Findings from the current study indicate that perceived stress may not only be an outcome of food insecurity but also a predictor of food insecurity. The relationship between perceived stress and food insecurity maybe cyclical, that is, each factor predicts and is predicted by the other. The link between perceived stress and food insecurity may be explained through different pathways – behavioral, instrumental and biological. For ART patients, perceived stress may be a result of living amidst multiple adverse conditions such as poverty, HIV/AIDS, and discrimination and stigma. These adverse living conditions may affect the motivation and ability of ART patients to work and earn income, which in turn, diminish access to food. The association between stress and food insecurity may also be due to limited or lack of instrumental support that provides food assistance to ART patients and their households. ART patients with higher perceived coping strategies may signify presence of a reliable social network – formal or informal – that

they can depend on when access to food is limited. On the contrary, ART patients with higher perceived mental distress may indicate a weak social support system to rely on when access to food is inadequate. In addition, PLHIV living with inadequate resources often experience stress levels that can cause the brain to produce hormones such as cortisol and epinephrine at quantities that may alter immune function or cause inflammation (Glaser, 2005; Godbout & Glaser, 2006; Kemeny & Schedlowski, 2007; Yang & Glaser, 2002). The effect of sustained exposure to stress-induced hormones may be more harmful to individuals with already deficient immune system. The “wear and tear” effect may exacerbate PLHIV’s health and increase their risk of other chronic and infectious diseases (Godbout & Glaser, 2006; Yang & Glaser, 2002). The adverse effect of stress on PLHIV’s health can make them sicker and reduce their capacity to work and earn income, which in turn, reduces resources to access food.

In summary, household economic factors remain to be strong predictors of food insecurity. Consistent with prior research, food insecurity is a problem related to poverty and lack of material security in the household. Improving a household’s economic standing can increase a household’s access to food. In addition, certain risk factors that increase susceptibility to food insecurity are more common among PLHIV contrasted with the general population without chronic health conditions. Compared with the general low-income population, PLHIV maybe more likely to get sick and hospitalized frequently, experience stigma and discrimination, and lose social support system. All these factors heighten their vulnerability to food insecurity. Finally, non-economic factors such as gender, education, household size and perceived stress may also be important to consider when developing programs to reduce food insecurity among PLHIV.

Food Insecurity and Optimal Adherence to Antiretroviral Therapy

The third research question of this dissertation investigated the relationship between food insecurity and ART adherence among PLHIV in rural Zambia. Research in SSA reveals that food insecurity is negatively associated with optimal treatment adherence (Hong et al., 2014;

Musumari et al., 2014; Singer et al., 2015). Food-insecure ART patients are less likely to adhere to treatment optimally, which in turn, heightens adverse health outcomes including higher risk of mortality (Weiser et al., 2014; Young et al., 2014). Despite existing research that shows robust association, few studies have examined the relationship between food insecurity and HIV treatment adherence among ART patients in Zambia, particularly in rural communities such as Lundazi and Lumezi.

Overall, study findings are consistent with prior research that suggests inverse association between food insecurity and optimal ART adherence. Across primary and sensitivity models, food-insecure patients were less likely to adhere to ART optimally. Food insecurity decreased the likelihood of optimal ART adherence, irrespective of how ART adherence was measured (whether self-report visual analog scale or medication possession ratio based on pharmacy information). Similarly, results are identical across different optimal adherence thresholds. Food security negatively affected ART adherence whether the optimal threshold was set at $\geq 95\%$, $\geq 90\%$ or $\geq 80\%$ level. Furthermore, regardless of how food insecurity was defined – whether the variable was continuous, binary or categorical, results are consistent and indicate that food insecurity is an important barrier to optimal antiretroviral therapy adherence. Results also indicate that the probability of achieving optimal ART adherence further decreases as the severity of food insecurity increases. For instance, moderately food insecure ART patients were 86% less likely to be adherent to ART (measured using MPR) compared with mildly food insecure or food secure ART patients. On the other hand, severely food insecure ART patients were 95% less likely to achieve optimal ART adherence (measured using MPR) compared with mildly food insecure or food secure ART patients.

Although the pattern is consistent across various model specifications and with similar studies in SSA, none of the associations between food insecurity and optimal ART adherence in this study are statistically significant based on two-tailed test. If one-tailed test is used, however, a number of associations approach statistical significance. These findings suggest that the

relatively small sample size of the study may not be adequate to detect statistically significant relationships. Increasing the sample size may increase the significance level of the association between food insecurity and ART adherence.

As explained in Chapter 1, a number of pathways explain why food insecurity predicts suboptimal ART adherence. The four most common mechanisms through which food insecurity adversely affects adherence behaviors include: 1) the belief that when on ART adequate food should be eaten to optimize treatment outcomes; 2) intolerable hunger due to increased appetite from being on ART; 3) severe side effects of ARV drugs when taken without food; and 4) competing demands to either put food on the table or pay for ancillary treatment costs (Young et al., 2014; Singer et al., 2015). All these events could have been (or continue to be) experienced by ART patients in the current study. For instance, conversations with ART patients in Lundazi District indicate that unbearable side effects (such as severe forms of headache, stomach pains and fainting) force them to skip doses; and they resume taking medications after they start feeling better (Victor Nyirenda, personal communication, March 23, 2015). Even though they recognize the importance of taking their medications as prescribed, severe side effects due to taking ARV drugs on an empty stomach may dissuade PLHIV from adhering to ART optimally.

In addition, many ART patients in the study struggle to meet basic household needs because of minimal income. These patients also have to figure out how they will pay for ancillary treatment-related costs such as transportation to get from their homes to health facilities. In this study, the average time it takes to reach either Lumezi or Lundazi hospitals is 110 minutes (or roughly 2 hours) and with an average distance to either health facility of nearly 12 kilometers one-direction. Conversations with ART patients reveal that many of them fail to pick-up ARV drugs on-time because they often do not have extra money to get to the in-house pharmacy at Lundazi or Lumezi health facilities (Victor Nyirenda, personal communication, March 23, 2015). For many poor ART patients and their households, they face dilemmas when deciding how to allocate their limited financial resources – what household needs should be met and what needs

should be sacrificed. Consistent with evidence from other communities in SSA (e.g., Gari et al., 2014; Gusdal et al., 2009), ART patients in this study may either give up food and other basic household needs to continue treatment, or skip their medications in order to buy food and meet other urgent household needs.

Predictors of ART adherence beyond food insecurity. Based on theoretical and empirical evidence, various factors facilitate or hinder PLHIV's ability to take their ARV medications as prescribed (Atkinson & Petrozzino, 2009; Langebeek et al., 2014; Mills et al., 2006; Reda & Biadgilign, 2012). Although food insecurity was not a statistically significant predictor of optimal ART adherence, a number of covariates were either statistically significant or demonstrated statistical significance. Geographic residence, ownership of transport-related assets and health perception were significant predictors of optimal ART adherence measured using the 30-day visual analog scale. In this same model, the relationship between livestock ownership and ART adherence demonstrated statistical significance. Lumezi residents were less likely to be adherent to ART optimally compared with Lundazi residents. One potential explanation to this finding is the disparity on food and economic security between respondents from Lumezi and Lundazi. For instance, the two sites differed on the prevalence categories of baseline food insecurity, with Lumezi having a substantially higher proportion of severely food-insecure ART patients (92%) than Lundazi (57%). In general, Lumezi patients were more likely to be food insecure than Lundazi patients. Similarly, in terms of income, Lumezi residents had lower income than Lundazi residents. Lumezi residents also had fewer assets and worse financial situation than Lundazi residents. The lack of food and economic security among Lumezi residents may prevent them from taking their medications as prescribed.

Based on baseline VAS, asset ownership appears to have mixed effects on optimal ART adherence. The association depends on the type of asset. ART patients who owned more transport-related assets were less likely to achieve baseline optimal ART adherence than ART patients with fewer transport-related assets. On the contrary, ART patients who owned more

livestock were more likely to be adherent to treatment optimally than their peers who own fewer livestock. This mixed relationship may be explained through several characteristics associated with each asset type. First, livestock is more directly connected to food than transport-related assets. Livestock provides an immediate source of food. ART patients and their households may rely on some of their livestock (particularly smaller animals such as chickens which was the most commonly owned livestock in the sample) to feed and nourish them. As explained earlier in this section, ART patients may be more motivated to take their medications as prescribed if there is available food because of the belief that food is required to maximize treatment efficacy and avoid acute drug side-effects. However, having livestock may not routinely provide adequate access to food. Evidence suggests that households in SSA do not automatically divest their assets to maintain household consumption (Dercon, 2005; Fafchamps, Udry, & Czukas, 1998; Hoddinott, 2006). In some cases, the decision to sell livestock depends on the type of economic shock (Hoddinott, 2006; McPeak, 2004). The findings suggest that having *more* livestock increases the ability of ART patients and their households to cope with food insecurity and smooth consumption patterns, while at the same time maintain enough livestock for income generation.

Second, ownership of transport-related assets may indicate two things: a) these assets are used for income-generation; and b) people who own more transport-related assets have higher socioeconomic status. The first point implies that when transport assets are used to generate income, ART patients may become too occupied transporting people or goods that they forget to take their medications as prescribed. Also, if using transport assets require spending some time away from home, ART patients may forget to bring their medications with them, or if they bring their medications, they may not want to take ARV drugs in front of people who do not know about their health condition. In turn, these situations constrain PLHIV from taking their medications optimally or as prescribed. The second point suggests that ownership of more transport-related assets may signify higher socioeconomic status. At baseline, 25% of study

participants owned one type of transport-related asset (e.g., bicycle, motorcycle, other motor vehicles such as cars or trucks, and ox cart), and 5% owned two types of transport assets. For ART patients who have higher socioeconomic status, taking their ARV medications may be challenging especially if they have not disclosed their HIV-positive status to people around them. They may feel that they have a lot to lose if people find out about their conditions, and because of fear and stigma, they may avoid taking their medications in public or at their workplace. These circumstances, in turn, reduce PLHIV's ability to adhere to ART optimally. In other words, the negative relationship between ownership of transport-related assets and optimal ART adherence may be an indicator of stigma and fear, which in turn, inhibit PLHIV (particularly those of higher socioeconomic status) from disclosing their status and living at will (including bringing and taking their medications to work).

In addition to geographic residence and assets, self-perceived health status predicted optimal ART adherence when measured using VAS. ART patients with better self-perceived health were more likely to adhere to ART optimally than ART patients with poorer self-perceived health. Health perception or self-perceived health is a subjective measure that taps into one's own perspective of his or her overall state of healthiness (Jylhä, 2009). Better health perception indicates a positive assessment of one's own health, including subjective and objective aspects. On the contrary, poor health perception suggests a negative evaluation of one's own health. ART patients with positive health perception may feel better about their overall health and attribute their better health to ART, particularly taking their medications as prescribed. Positive health perception may further motivate PLHIV to adhere to ART optimally because they see beneficial effects of HIV treatment on their health. The reverse may be true for ART patients with poor self-perceived health. Their negative health perception may be a result of not feeling well in spite of being on ART. Consequently, negative self-perceived health may discourage PLHIV from believing that ART benefits their health, which in turn, leads to skipping doses and failing to adhere to treatment.

When adherence was measured using medication possession ratio, no covariate was consistently significant (or approached statistical significance) across all three adherence thresholds – $\geq 95\%$, $\geq 90\%$ and $\geq 80\%$. Nonetheless, a few covariates stood out including education level, debt, ART treatment duration, distance to health facility and time to travel to health facility. The direction of association between these variables and optimal ART adherence was consistent across the three adherence thresholds. First, ART patients with secondary or higher education were less likely to be optimally adherent than ART patients with primary education. ART patients with more education may have more stable jobs that may prevent them from picking up their ARV prescriptions on-time, which in turn, forces them to miss or skip doses. Also, ART patients with more education and stable jobs may worry about their status being disclosed if they have a scheduled time away from work to pick-up their ARV medications. Fear of disclosure, stigma and discrimination may compel them, for instance, to forego their regular pick-up schedules and miss required doses. Second, ART patients who owed money were less likely to be optimally adherent than ART patients who did not owe money. In many cases, debt is a sign of financial struggle and not having enough resources to meet household needs. ART patients with debt may not have sufficient money to pay, for instance, transport costs to get to the health facility and pick-up ARV prescriptions, which in turn, leads to missing required HIV treatment doses. Third, treatment duration negatively influenced optimal ART adherence, albeit minimally. Findings suggest that PLHIV who have been on ART for a longer period of time are less likely to achieve optimal treatment adherence than their peers who have been on ART for a shorter duration. Treatment fatigue may set in for ART patients who have been on ART for an extensive period of time. Regardless of ART's effects on their health, these patients may become unmotivated or tired after taking ARV medications for years. Treatment fatigue, in turn, may discourage ART patients from picking up their prescriptions regularly which eventually lead to missing treatment doses. In addition, it is possible that when ART patients have been on treatment for a longer period of time, they feel much better and the motivation to

take ARV drugs diminishes. However, when they get sicker and their CD4 count substantially decreases, they may become more adherent and pick-up their medications more regularly.

Consistent with prior research (e.g., Reda & Biadgilign, 2012; Skovdal et al., 2011), health facility characteristics influence adherence to ART. In this study, distance to health facility and time to travel to health facility have contrasting effects on optimal ART adherence measured using MPR. Distance to health facility was negatively associated with ART adherence, whereas time to travel to health facility was positively associated with ART adherence. ART patients who lived farther from the health facility were less likely to achieve optimal ART adherence compared with their peers who lived nearer to the health facility. In this study, the average distance to health facility was 11 kilometers and 18% of the study sample lived at least 20 kilometers away from either Lumezi or Lundazi hospitals. For many ART patients who live far from the health facilities, going to pick-up their medications at regular intervals may mean taking time off from work, paying transport costs and expending energy. These challenges may discourage ART patients to pick up their medications on-time, which in turn, forces them to miss treatment doses. On the other hand, PLHIV who require longer time to travel to a health facility are more likely, albeit marginally, to achieve optimal ART adherence than their counterparts who require shorter time to get to a health facility. Conversations with ART clinicians may illuminate this counterintuitive finding. Based on these conversations, ART patients who require longer travel time to pick-up their medications may be given a longer supply of ARV drugs, which in turn, saves them 1-2 trips to the health facility (Victor Nyirenda, personal communication, September 18, 2015). For example, instead of a regular 3-month supply, these patients may receive a 6-month supply. The extra supply of ARVs and reduced number of trips to the health facility may encourage ART patients who require longer travel time to pick-up their medications as scheduled. In this study, living far does not automatically mean longer travel time to health facilities. It is possible that those who live far have shorter travel time if they use a mode of transport to get them to the health facilities. On the contrary, it is

possible that those who live relatively “close” to the health facilities (e.g., not less than 5 kilometers) have longer travel time if they walk and do not use a mode of transport to reach the health facility.

Food insecurity and poverty. In all multivariable models, other poverty indicators were added as covariates when examining the association between food insecurity and ART adherence. Results are consistent across all models and indicate that food insecurity has a negative effect on optimal ART adherence controlling for other indicators of poverty such as income, assets, debt, education level and type of occupation. These findings suggest that the effect of food insecurity on ART adherence is not a proxy or substitute for income or other poverty indicators. In other words, food insecurity has an independent (negative) association with optimal ART adherence. This constant pattern across primary and sensitivity models, various definitions of food insecurity and multiple measures of adherence is not unexpected. An emerging body of qualitative and quantitative research in SSA and elsewhere in the world has shown a consistent and inverse relationship between food insecurity and optimal ART adherence (Hong et al., 2014; Singer et al., 2015; Young et al., 2014). In addition, distinct conceptual pathways explain how food insecurity affects ART adherence. These pathways provide solid theoretical support that link food insecurity with inability of ART patients to take their medications as prescribed, and differentiate food insecurity from other poverty indicators (notably, income). These conceptual links (perceived food requirements of ART, increased appetite and hunger, severe side effects, competing demands, medication diversion, and mental health effects) are supported by empirical evidence in resource-limited and resource-adequate settings. In summary, strong theoretical and empirical evidence support the relationship between food insecurity and ART adherence.

Impacts of Health and Wealth

The fourth research question of this dissertation examined the direct impacts of *Health & Wealth* program on two key outcomes: food security and optimal ART adherence. The

evidence on the effects of *Health & Wealth* aims to address substantial gaps in research in the area of integrated livelihood and HIV treatment. This research question attempts to investigate potential causal links between a pilot household economic-strengthening intervention and health outcomes of economically vulnerable ART patients. Although prior programs address inadequate access to food among PLHIV on ART in Zambia and elsewhere in SSA (e.g., Cantrell et al., 2008; Rawat et al., 2014), most interventions reflect a biomedical approach to addressing the downstream consequences of food insecurity such as malnutrition. Few published studies, particularly in rural Zambia, have addressed the upstream causes of food insecurity, such as lack of income, assets and other livelihood sources. In addition, fewer livelihood programs targeted to ART patients have been systematically evaluated to determine effects on key outcomes, including food insecurity and optimal ART adherence.

Health & Wealth was a pilot integrated HIV treatment and livelihood program implemented in rural Zambia. The pilot program was designed to test the feasibility and effects of a household economic-strengthening intervention on the wellbeing of ART patients. *Health & Wealth* purposely combined various components to address the cumulative risk mechanisms that negatively influence wellbeing of PLHIV. These risk mechanisms include low income, limited assets, food insecurity and poor psychosocial outcomes, which in turn, adversely affect HIV treatment-related behaviors such as ART adherence. The intervention comprised of economic motivations (cash transfer to purchase an income-generating asset and access to a savings account), knowledge building (through financial education and small business management training), and health education (food and nutrition and ART adherence counseling). Inclusion of these components was informed by theoretical models and previous research (e.g., de Pee et al., 2014; Chowa, Masa, & Sherraden, 2012; Martinez et al., 2014; Weiser et al., 2010) in the field of integrated livelihood and asset development in sub-Saharan Africa and other resource-limited settings. ART patients in Lumezi received the intervention in addition to ARV medication counseling. ART patients in Lundazi received ARV medication

counseling only. The training component (food and nutrition, financial education and small business management) of the intervention lasted one week. Seba savings accounts from ZANACO Bank were opened after the training. Cash grants were directly deposited into participants' accounts in two installments of K700 (August 2015) and K500 (January 2016).

Impact findings indicate positive effects of *Health & Wealth* on both outcome variables. At midpoint follow-up (eight months after baseline and two months after the training was delivered), treatment (intervention) participants were more food secure and optimally adherent to ART contrasted with control participants. These positive results were generally consistent across various models – whether findings were unadjusted or adjusted bivariate and multivariate and whether the number of multiply imputed datasets were 5, 20, 50 or 100. However, only the positive effect on food insecurity was consistently statistically significant across bivariate and multivariate models. None of the positive effect on optimal ART adherence was statistically significant.

As mentioned earlier, *Health & Wealth* was one of the first IHLPs to address barriers to food security and optimal HIV treatment adherence among economically poor ART patients in rural Zambia. The program provided tangible resources to generate income that can be used to buy or purchase food, skill-building opportunities to develop and sustain livelihoods, and knowledge-building sessions to enhance health-related awareness. Previous studies from Zambia and other resource-limited settings found that food assistance delivered as part of HIV care can improve food security and ART adherence (Byron et al., 2008; Cantrell et al., 2008; Martinez et al., 2014; Rawat et al., 2014; Tirivayi & Groot, 2011). Recent evidence has also shown that household economic strengthening programs delivered on its own (Banerjee et al., 2015) or as part of HIV care (Weiser et al., 2015) can increase food security. Further, when integrated with HIV care and treatment, livelihood programs can positively influence ART-related outcomes such as higher CD4 counts and viral load suppression (Weiser et al., 2015). Findings from *Health & Wealth* extend the body of evidence by demonstrating that a potentially

sustainable income-generating and financial intervention with a cash transfer component improved food security and ART adherence for HIV-infected individuals. These findings support prior research that indicates the critical role of food security and poverty alleviation in improving health outcomes.

Food security. The positive effect of *Health & Wealth* on food security may be due to a single or multiple aspects of the intervention. For instance, the cash transfer component might have given participants a new source of cash flow that they used to purchase food. It is possible that participants set aside a portion of the cash grant they received to buy food and smooth their consumption patterns. Because of the high vulnerability of treatment participants to food insecurity due to very low income, the more likely it is that the cash transfer will have a positive impact on participants' ability to obtain food. At baseline, treatment (Lumezi) and control (Lundazi) participants differed on income – with Lumezi participants being more income-poor than their Lundazi counterparts. However, the groups were comparable on their baseline food insecurity scores. It is also probable that the first installment of cash transfer (deposited in August 2015) freed up financial resources, which in turn, allowed the household to have extra money to buy food. For instance, cash or savings (before cash transfer) might have been budgeted to pay for other expenses or investments (e.g., to purchase livelihood inputs). After cash transfer, these same financial resources might have been reallocated to purchase food because the cash grant will cover the original (pre-cash transfer) expenses. Another possibility is that improved food security was the result of higher income from livelihood or income-generating activities that were financed by the cash grants. Participants could have used the money, as intended, to start income-generating activities. Although the first cash grant installment was deposited in August 2015 (or a month before the midpoint survey), it is still likely that treatment participants began (or recapitalized) their income-generating activities, which were mostly retail-oriented, and produced monetary returns. Retail-oriented businesses such as buy and sell of goods consistent with those desired by participants (Victor Nyirenda,

personal communication, June 12, 2015) might generate income quicker than other types of livelihood activities (e.g., farming and livestock-raising). In turn, income from these livelihood sources might have been used to satisfy household needs including food.

In addition to the cash transfer component, it is possible that the knowledge-building workshops contributed to better food security for Lumezi participants. From the financial education and business management training, the treatment group might have learned how to set aside money and prepare a financial plan that meets household needs, as well as how to use income from livelihood activities to meet (business and) household basic needs such as food. The food and nutrition component might have also reminded participants the importance of adequate food and proper nutrition to maintain good health. In turn, this health aspect of the intervention might have motivated participants to prioritize access to food, for example, through reallocation of existing financial resources. However, the potential role of knowledge development on improving food security may not be reasonable if participants do not have sufficient income or other financial resources that they can use to meet their needs. In other words, the ability of these training sessions to positively influence food security might have been augmented by access to additional cash provided by the program. Alternatively, knowledge building alone might not have beneficial effect on food security if participants did not receive the cash transfer. Unfortunately, this pilot study was not able to isolate the effects of *Health & Wealth*'s individual components on food security. The findings do not tell us whether improved food security is because of the cash transfer alone or in tandem with knowledge-building.

ART adherence. The positive effect of *Health & Wealth* on ART adherence may be attributed to a single or multiple aspects of the intervention. An evident explanation could be that the cash transfer and additional income from livelihood activities allowed ART patients to access food and pay for HIV treatment-related costs, which in turn, positively influence ART adherence. Economic resources that ART patients and their households accumulated because of the program might have increased the capacity of ART patients to overcome financial-related

barriers to optimal ART adherence, including limited income to obtain food regularly. Food security is a critical barrier to ART adherence and has been found to have an enabling effect in improving HIV treatment and related outcomes (de Pee et al., 2014; Weiser et al., 2011; Young et al., 2014). Given what we know from the literature, access to food is one of the (alterable) risk mechanisms targeted by the *Health & Wealth* program. One of the program assumptions was that providing the treatment group with access to cash grants (as well as relevant training) to start (or boost) a livelihood would increase income. Increasing income, in turn, would allow ART patients to have adequate financial resources to obtain food (and meet other household needs) in a more sustainable manner. Furthermore, adequate material resources such as income cushion ART patients from experiencing high levels of stress or anxiety, which in turn, negatively affects adherence to HIV treatment. In addition to mediating relationships, there could be a direct link between participation in *Health & Wealth* and optimal ART adherence. For instance, program participation might motivate ART patients to take their medications because they recognize the value of getting healthier in order to start a livelihood. For treatment participants, it is possible that *Health & Wealth* offers them a new beginning and/or a tangible opportunity to create and plan for a more economically viable future. Consistent with the literature (Bassett, Wilson, Taaffe, & Freedberg, 2015; Galárraga, Genberg, Martin, Laws, & Wilson, 2013; Haff et al., 2015; Lagarde, Haines, & Palmer, 2009), these economic incentives might have a facilitating effect on health behaviors, including optimal ART adherence.

Beyond financial incentives and economic motivations, other aspects of the program might have a direct influence on ART adherence. For instance, the group training component of *Health & Wealth* exposed program participants with other ART patients like them. It is possible that subsequent interaction among participants included discussion about the challenges to ART adherence because of numerous reasons such as inadequate access to food. For some participants, it is possible that seeing other food-insecure ART patients adhere to treatment optimally might have increased their beliefs about their personal efficacy to follow treatment

recommendations in spite of food insecurity. During the intervention training, participants might have also encouraged each other to take their medications as prescribed despite various challenges. For instance, by hearing stories and learning about different coping strategies, participants might have been inspired by their fellow ART patients. Consistent with social cognitive theory (Bandura, 1998), learning by observation and social persuasion are powerful tools that can influence people's belief about their own self-efficacy, which in turn, affect behaviors (in this case, ART adherence). Finally, the “booster” session on ART adherence might have directly contributed to the higher rate of optimally adherent Lumezi (or treatment) patients than Lundazi (or control) patients. The additional training on the importance of taking medications as prescribed might have prompted treatment participants about the benefits of optimal ART adherence to health and wellbeing. Although Lundazi patients were provided medication adherence counseling (as part of usual care outlined by the Ministry of Health), the timing might not have been as recent as the additional session delivered as part of the *Health & Wealth* program. In other words, the timeliness of the “booster” session implemented as part of the intervention might have a more immediate and recent effect on ART adherence than adherence counseling given before or shortly after ART initiation.

In summary, it is likely that the intervention contributed to the higher rate of follow-up optimal adherence (albeit not statistically significant) in treatment than control site. It is also possible that an individual or multiple components of *Health & Wealth* positively influenced ART adherence. However, consistent with observed effects on food security, findings do not tell us whether improvement in the outcome of interest can be attributed to a specific program component or multiple aspects that when put together might have created a synergy to enhance HIV treatment outcomes. In other words, the pilot study design was not able to isolate impacts of individual components from other aspects of the *Health & Wealth* program.

Implications and Limitations

Policy Implications

Findings have important implications for policy. Food insecurity remains a critical social and public health issue in resource-limited settings including Zambia. Although the number of food-insecure individuals and households in the general population continues to be high, the overlap between food-insecure and HIV-positive individuals on ART is increasing as more PLHIV (including in SSA) get access to life-saving HIV medications. Previous studies in SSA have shown that more than 50% of PLHIV on ART are food insecure (Hong et al., 2014; Musumari et al., 2014; Tsai et al., 2011). In this pilot study, prevalence of food-insecure ART patients persists to be at least 90% at both baseline and follow-up. These findings suggest that, in many cases, the prevalence of food insecurity among ART patients is higher than the prevalence in the general population. This alarming trend requires policy and program interventions and indicates relevance of such interventions for a large segment of the population.

The integrated conceptual framework of food insecurity and ART adherence (explained Chapter 2) provides multilevel and interrelated “entry points” for program and policy development. Interventions should take into account the various mechanisms at the intrapersonal, interpersonal and environmental levels that explain how and why food-insecure ART patients are less likely to adhere to HIV treatment optimally. These mechanisms, which can also be classified as information-, motivation- or strategy-related can be targeted for enhancement or modification. In other words, appropriate interventions require identification and understanding of the malleable root causes of food insecurity, particularly inadequate access to food. Programs and policies that address underlying determinants of food security among PLHIV and their households are more likely to be effective and relevant than interventions that tackle symptoms or consequences of food insecurity. Although food insecurity in general can be triggered by a combination of factors at the macro and micro levels (e.g.,

poverty, environmental change, rising food prices, and insufficient agricultural production), findings from this study provide evidence of potential underlying causes of inadequate access to food at the individual, interpersonal, and environmental level. Consistent with prior research in SSA (e.g., Donovan & Massinque, 2007; McCoy et al., 2014; Tsai et al., 2011), food insecurity among ART patients in Lundazi District is an issue of household economic uncertainty and its effects on intrapersonal and interpersonal dynamics. Poor financial and economic situations characterized by having low income, fewer assets, and monetary debts increase the risk of food insecurity and may adversely affect individual beliefs and social relationships. All these factors associated with inadequate access to food may be improved by *Health & Wealth*, a pilot intervention that was designed to target alterable predictors of food insecurity at the individual, interpersonal and environmental level.

IHLs, like *Health & Wealth*, offer a feasible and potentially effective intervention that targets malleable predictors of food insecurity and barriers to ART adherence. A growing body of empirical evidence indicates positive effects of IHLs on household economic viability including higher income and enhanced food security. Beyond improving economic determinants of inadequate access to food, IHLs may have positive effects on HIV clinical outcomes and barriers to HIV treatment adherence other than food insecurity. Findings from *Health & Wealth* and other IHLs (e.g., Holmes et al., 2011; Holmes & Winskell, 2013; Wagner, Rana et al., 2012; Weiser et al., 2015) have demonstrated benefits on clinical outcomes (e.g., optimal ART adherence, higher CD4 counts, and lower viral loads), psychosocial wellbeing (e.g., lower perceived stress, and positive self-esteem, self-efficacy, and future orientation) and HIV stigma reduction (e.g., through promotion of economic productivity among ART patients and facilitation of socially acceptable ways to obtain food). In other words, IHLs represent an intervention model that targets cumulative risk mechanisms associated with food insecurity and poor HIV treatment outcomes.

Macro-level programs (e.g., governmental policy and private sector initiatives) that facilitate availability of food are also necessary to complement micro-level interventions that address limited access to food. The government and private sector should ensure stable and sustainable availability of food in the country. Interventions that promote improved access to food at the household or community-level may not be effective when macro-level challenges such as physical unavailability of food (for example, due to insufficient agricultural output, environmental change, etc.) and rising food prices are not addressed. For instance, interventions that promote livelihood development may not cope with rapid increase in food prices particularly if there is no corresponding increase in household income. In addition, having adequate financial resources to obtain food alone does not guarantee food security if food is physically absent at the marketplace or agricultural input is unavailable.

In Zambia, a potential policy and program “entry point” for IHLPs is through the National AIDS Strategic Framework. This revised framework (for 2014 – 2016) provides the country’s national response to HIV, as well as operational guidelines for prioritized HIV prevention and treatment strategies and interventions (NAC, 2014b). One of the framework’s priority strategies includes strengthening the food and nutrition component of ART programs. Currently, most food-related components focus on nutrition supplementation (and food assistance) to remedy malnutrition among PLHIV. However, the national framework recognizes the importance of increasing access to and coverage of community-based programs that incorporate food security into HIV treatment and care. In particular, the strategic framework calls for scaling up of comprehensive interventions, including high-impact models that address underlying determinants of malnutrition and food insecurity among PLHIV. In addition, IHLPs such as *Health & Wealth* closely aligns with the framework’s priority strategies in the areas of social protection, and poverty alleviation and livelihoods. The framework recognizes the value of interventions (such as *Health & Wealth*) that empower economically poor households to develop skills and acquire resources that foster self-reliance and resilience through sustainable

businesses and livelihood activities. Study results will also provide needed empirical evidence (insufficient evidence is cited as a critical gap in the strategic framework) to understand the significance of livelihood security in ensuring that PLHIV live longer through retention in treatment and care. In other words, findings from *Health & Wealth* may provide timely evidence to inform “mainstreaming” of IHLs into the country’s national strategy to improve HIV treatment and care.

Finally, government strategies (as outlined in the National AIDS Strategic Framework) reflect a “graduation model” approach. This approach is particularly relevant in places like Lundazi District where there is high prevalence of food insecurity and HIV/AIDS. A graduation model can first alleviate severe food insecurity and help undernourished PLHIV to regain their strength and energy by providing consumption support. After basic needs such as food have been met, household economic strengthening programs such as *Health & Wealth* can be introduced to assist PLHIV to enhance capabilities to develop livelihoods and enable stable and sustainable access to food. Macro-level policies are also needed to foster and sustain small business ownership and activities. For instance, government should provide small business owners with access to subsidized farming inputs and implements, appropriate technical training, and opportunities to expand markets. In other words, the graduation model combines micro, mezzo and macro strategies to promote sustainable livelihood and food security.

Practice Implications

Findings have important implications for practice. ART has transformed HIV from a life-threatening illness to a more chronic, manageable condition. This advancement in HIV therapy means that PLHIV can now live longer and healthier. However, access to ART alone is not sufficient to fulfill its benefits on survival and overall wellbeing. PLHIV are required to remain in treatment and care, including long-term adherence to ART. In order to ensure that ART patients remain in care and adhere to treatment optimally, barriers need to be recognized and removed. For social workers (and others in the health care profession) working with PLHIV,

they ought to know the barriers and how they can assist their clients in mitigating adverse effects of such barriers on health and treatment outcomes. One critical barrier to HIV treatment adherence (and other aspects of the HIV treatment cascade including ART initiation and retention in care) is inadequate access to food. For practitioners, it is necessary to know and understand why and how HIV increases the risk of food insecurity, including its negative impact on ART adherence. Social workers should also be familiar with coping strategies (both positive and negative) used by food-insecure PLHIV and identify how such approaches affect wellbeing. If coping mechanisms are positive, social workers should be trained on how to strengthen such mechanisms. If coping techniques are harmful, social workers should be equipped to minimize such techniques without stigmatizing PLHIV. Similarly, social workers should be trained to address fears of PLHIV about hunger and adverse effects of ART when food is not sufficient. Counselling sessions should include potential strategies to tackle and overcome various mechanisms in which food insecurity can interfere with treatment adherence. Social workers and other practitioners should also be knowledgeable of readily available services that provide food to food-insecure PLHIV or be able to issue referrals for food support. These practice implications are consistent with the social work profession which requires practitioners to have accurate and up-to-date knowledge of economic and health factors that facilitate human development and individual capacity for better social functioning, particularly among the most vulnerable populations. In addition, these practice recommendations can help social workers to be more effective social service providers and advocate for PLHIV.

Furthermore, the implementation of *Health & Wealth* has relevant practice lessons. First, livelihood interventions and their components should be appropriate for PLHIV. For instance, labor-intensive activities may not be suitable for PLHIV with limited strength and stamina. PLHIV who are severely malnourished, clinically unstable, or in the advanced stages of HIV infection may not have the physical capacity to attend various training sessions and undertake livelihood activities. For these groups of ART patients, it may be more judicious to

provide nutrition supplementation and then transition them to livelihood programs after they have been rehabilitated and regained physical capacity. In addition to health conditions, program components of IHLPs should be relevant to socioeconomic status of target populations and their local contexts. For instance, a livelihood program that focuses on better farming techniques to increase output and requires ownership of land to be able to participate will eliminate landless PLHIV. Exclusion of economically poor individuals may exacerbate their already disenfranchised status and pull them downward to more severe and chronic forms of poverty. Consistent with the development of *Health & Wealth*, program planners need to be innovative and engaged with community stakeholders to identify locally feasible and viable income-generating activities.

Second, partnerships with local stakeholders particularly health facility personnel is critical for building trust with PLHIV and success of the program. For instance, treatment supporters at Lumezi Mission Hospital (intervention site) played a valuable role in assuring participants of confidentiality and potential benefits of the program.²³ In addition, recruitment and participation in the program were successful because we were able to utilize treatment supporters in the process. In the initial stages of recruitment, our project manager expressed that we were not able to recruit as much participants as planned (Victor Nyirenda, personal communication, December 14, 2014). He explained that stigma associated with being HIV positive prevented prospective participants from consenting because they did not know him and were concerned about confidentiality and disclosure of HIV status. To address these concerns, we requested the assistance of treatment supporters who have existing relationships with potential participants. With the treatment supporters' help, recruitment increased and enough participants consented to meet the desired sample size. Because participants trusted them, treatment supporters were also instrumental in locating and monitoring participants

²³ In Lundazi District, treatment supporters include ART patients and clinic staff. Treatment supporters help ART patients cope with HIV therapy.

throughout program duration, which in turn, minimized program and data collection attrition. Although recruitment and uptake of programs and social services in general can be challenging due to various reasons, working with populations that remain highly stigmatized require innovation and partnership with trusted stakeholders to guarantee success. These lessons highlight the importance of building trust with participants and overcoming stigma.

Research Implications

Findings have important implications for research. First, endline (or the third data collection point) will be collected in March 2016. Endline data will provide evidence on whether treatment effects on food security and ART adherence that were observed eight months after baseline and two months after intervention training will change or be sustained. Endline data will be collected 12 months after baseline and six months after intervention training. These intervals may provide adequate lag time to allow possible effects of the intervention, particularly on food security, to occur or be maintained. The longitudinal nature of the data will also help determine the trajectories of food security and ART adherence, particularly whether they remain linear or become nonlinear.

Second, endline data will allow me to answer additional research questions related to food insecurity and ART adherence that could not be answered with data from baseline and brief midpoint surveys. For example, I can test the mediating effect of food security (collected at midpoint) on the relationship between *Health & Wealth* participation (collected at baseline) and optimal ART adherence (collected at endline). With three data collection time points, temporal order will be established to adequately examine potential mediating relationships. Also, posttest MPR data based on pharmacy dispensation information will be available at endline. Having posttest MPR data will allow me to examine the intervention's impact on optimal ART adherence based on a more objective data-gathering method. Results may supplement and validate current impact findings based on self-reported adherence data using a 30-day VAS.

Third, a larger study with experimental design is needed to definitively establish causal relationships. Although *Health & Wealth*'s research design was more rigorous than previous intervention studies, study findings are weakened due to lack of randomization which limits causal inference. A larger-scale experiment should also take into account the cluster-level effects due to the group-based training delivery and clustering of ART patients within health facilities. Although potential cluster effects were considered in the pilot study's design (for example, selection of two comparable health facilities and assignment of one health facility as treatment site and the other one as control site), the inclusion of only two health facilities (or communities) could not conclusively separate intervention effects from cluster-level variables – whether these factors exist at the health facility or community levels. In other words, these research next steps highlight the need for a larger-cluster randomized experimental study. A larger cluster-randomized design should also be able to address the inability of the pilot *Health & Wealth* study and previous intervention studies to isolate impacts of individual components from other aspects of the program or test the effects of different food security-related components.

Finally, in addition to research methodology, the pilot study provides valuable lessons for operational aspect of intervention research with PLHIV in resource-limited settings. Consistent with implications for practice, partnership with local and trusted stakeholders is critical to successfully implement research procedures. As stated in implications for practice, treatment supporters played a key role in recruiting participants and assuring their privacy and confidentiality. Treatment supporters also assisted in locating and tracking program participants, which in turn, lessened data collection attrition. In addition to treatment supporters, ART clinicians were instrumental in implementing data collection procedures. ART clinicians in Zambia are knowledgeable about the SMART Care system and other HIV treatment-related information. Clinicians are up-to-date with data that are routinely collected at the clinic and pharmacy, which in turn, facilitate timely abstraction of clinical and pharmacy

data. The use of existing (and more objective) clinical and pharmacy data also minimized potential observer effect in which participants may improve their behaviors or modify their responses due to their awareness of being observed. In sum, lessons from the pilot *Health & Wealth* study demonstrate importance and feasibility of collaboration with local partners to conduct multi-method research procedures with a highly-stigmatized population.

Strengths and Limitations

Contributions to the literature. This dissertation expanded what we know about food insecurity and ART adherence among PLHIV in rural Zambia. Dissertation findings shed light on the extent of food insecurity, as well as protective and risk factors associated with inadequate access to food among ART patients in rural areas of Zambia. Study results also support the inverse relationship between food insecurity and ART adherence in SSA, and extend the literature by demonstrating evidence from rural communities in Zambia. In addition, impact results contributed to the IHLP literature by generating empirical evidence and addressing methodological weaknesses of prior studies. As of this writing, *Health & Wealth* remains one of few published IHLP studies to use a control group with pre- and post-test measures. In particular, no IHLP in Zambia has been systematically evaluated to determine effects on health and wellbeing of PLHIV. Current evidence from Zambia has come mostly from evaluation of short-term food assistance programs (e.g., Cantrell et al., 2008; Tirivayi et al., 2012). Most of these published studies have been implemented in urban areas such as Lusaka, and fewer studies have been conducted in rural areas such as Lundazi District in Eastern Province.

In addition, the pilot study considered potential diffusion if ART patients from the same health facility were randomized into treatment or control groups. To avoid treatment diffusion (and other potential threats such as resentful demoralization and compensatory equalization on the part of control conditions), the study design included two comparable health facilities in Lundazi District and assigned each one to either intervention or control site. The selection of two health facilities also attempted to take into account potential variation at the health facility

or community-level that may affect health and wellbeing outcomes of PLHIV. However, with only two communities or health facilities, there was not enough variation in community or health facility variables that could be included as covariates in the statistical models.

Unlike experimental studies, drawing causal inferences in observational studies that lack random assignment is challenging because treatment and control groups may not be comparable on observed and unobserved characteristics. Given this limitation, more rigorous analytical methods than conventional covariance control or regression models were used in this dissertation to estimate potential impacts of *Health & Wealth*. For instance, the treatment effect model adjusts for heterogeneity of program participation (or selection bias) by controlling for covariates hypothesized to affect selection bias. In addition, multiple imputation was conducted to take into account missing data due to program and measurement attrition. Missing data analysis was implemented to minimize potential bias in the findings due to reduction in sample size. Furthermore, sensitivity models were tested across research questions to compare and validate results based on different model assumptions. Although study findings do not prove causality, consistency of results suggests validity of observed associations across all research questions. For instance, consistency of observed effects supports the conclusion that Health & Wealth, or the conditions associated with the intervention, are important predictors of food security for ART patients in the treatment site. Finally, the pilot study used multi-method and longitudinal data collection techniques to increase reliability and validity of key constructs. For instance, ART adherence was measured using participant self-reported data and pharmacy dispensation information. The use of two adherence measures – both of which are commonly used in resource-limited settings – might increase the validity of ART adherence data and verify consistency of findings based on data collection method. Inclusion of a more objective ART adherence measure also offset the limitations of self-reported data such as susceptibility to recall and social desirability bias. In addition, the use of pharmacy records and other data routinely collected by health facilities in this dissertation indicates feasibility of using unobtrusive

outcome measures, which in turn, may reduce reactivity to the research project (i.e., awareness that their behaviors are being studied and measured).

Limitations: Research design. Although the pilot *Health & Wealth* program addressed some methodological weaknesses of prior observational and intervention research studies, careful interpretation of findings presented in this dissertation is recommended given study limitations. First, the study's research design is weak in its ability to definitively confirm causal relationships. Although statistical associations and temporal orders were purposely established in all analytical models (except models that investigated determinants of food insecurity as outlined in research question 2), the nonrandomized design does not rule out alternative causal explanations. Causal inference in quasi-experimental studies is more challenging because differences between groups may be more systematic, and thus, any observed effects may not be due to the intervention alone or may occur for reasons unrelated to treatment. This issue is highlighted by the significant baseline differences between intervention and control participants including ART adherence based on MPR. Threats to internal validity such as selection bias and attrition may also distort true relationships among study variables, including treatment effects of *Health & Wealth*. Furthermore, analyses based on cross-sectional data (e.g., research question 2 models) have additional limitations such as reverse causality. Cross-sectional, correlational studies provide the weakest evidence in establishing potentially causal relationships because temporal precedence is unclear. Lack of temporal order may alter true direction of the relationship. In research question 2, for instance, food insecurity may be predicted and a predictor of perceived stress. Both variables were measured at baseline. In addition, and as mentioned in implications for research, the pilot study's research design was not able to isolate effects of individual components from other aspects of the program. Findings could not tell us whether observed treatment effects were due to a particular component of *Health & Wealth* (e.g., cash transfer or skills training) or a combination of program elements.

Limitations: Sample size and statistical assumptions. Second, this dissertation has a number of weaknesses related to statistical conclusion validity or the inferences made about the correlation between and among study variables. The relatively small sample size (particularly the number of ART patients) might affect statistical power. For instance, the lack of statistically significant associations between key variables (e.g., food insecurity and ART adherence) might be attributed to the small sample size of the study and its impact on ability to detect a true effect. Low statistical power (due to small sample size) may also result in overestimation of effect size (when a true effect is observed), low probability of finding true effects (including positive research finding), and low reproducibility of results (Button et al., 2013; Cohen, 1988; Shadish et al., 2002). Small sample size also limited the number of covariates that could be included in multivariable statistical models. In a study with relatively small sample size, parsimony and consistency of findings, as well as avoiding model overparameterization, were taken into account when deciding the number of covariates to be included. In other words, the number of covariates was proportional to sample size. In addition, analytical models might have violated statistical assumptions particularly independence of observations. Because ART patients attend the same health facility, their data are clustered and the assumption of independent observations in linear or generalized linear regression models is violated (Raudenbush & Bryk, 2002). One consequence of a regression model that fails to adjust for clustering of data is biased standard errors, which make a finding spuriously significant (Guo, 2003). However, with only two health facilities in the pilot study, there was not enough number of health facilities and variation of health facility or community-level variables to be meaningfully included in statistical models.

Furthermore, statistical methods come with limitations. Although the treatment effect model is useful in producing better estimates of average treatment effects, these effects are based on assumptions that might or might not have been present in the study. Two critical assumptions include knowing the causes of selection processes (in this case, *Health & Wealth*

participation) and correctly specifying these causes in the selection equation. When key selection variables are excluded in the selection equation, treatment effect model results are biased (Guo & Fraser, 2014). In other words, the treatment effect model is sensitive to model “misspecification” (i.e., when the predictors are incorrect or omitted). Although the literature guided variable selection, it remains challenging to accurately classify the baseline characteristics into covariates that affect: both treatment assignment and outcomes (or true confounders), outcomes only (or potential confounders), or treatment assignment only. Also, application of the treatment effect model after multiple imputation of missing data is currently available to continuous outcome variables only. Because of this limitation, binary outcomes (particularly optimal ART adherence) were not analyzed using treatment effect model after multiple imputation. Alternative methods of estimating treatment effects using propensity scores after multiple imputation are described in the literature (e.g., Hill, 2004; Mitra & Reiter, 2011, 2016). However, implementation of these methods in Stata statistical software is currently not widely available.

Although application of missing data analysis using MICE followed best practices suggested in the literature, the procedures could still be incorrect and might bias study findings. One critical limitation is omission of important predictor variables in the imputation model. In many cases, the imputation model should be more general than the analysis model in order to capture more associations between the variables (Enders et al., 2006; Graham, 2009). However, the small sample size of the study limited the number of variables that could be included in the imputation model. Large number of variables, particularly categorical predictors created models that failed to converge. Small sample size also became a problem when adding interaction terms in the imputation model. The lack of interaction terms might have biased results. Furthermore, although the MICE approach offers numerous practical advantages over multivariate normal model (see for example, Bouhlila & Sellaouti, 2013), MICE lacks a strong theoretical underpinnings and can be tedious, especially when the imputation model is large. Nonetheless,

sensitivity models that demonstrated consistency or stability of findings across various specifications might have minimized some limitations due to selection of particular statistical methods (e.g., treatment effect model after MICE) over possible alternatives.

Limitations: Measurement. Third, although key constructs (in this case food insecurity and ART adherence) were clearly defined in this dissertation, a number of measurement-related issues might affect overall construct validity. Food insecurity in this dissertation only measured the access component of this multidimensional construct. Study findings do not tell us about actual food intake or food utilization of ART patients. Although the focus on access to food is reasonable given malleable predictors targeted by the intervention, actual food intake is equally important for PLHIV given the importance of nutrition for HIV therapy efficacy and their overall health, especially prevention of HIV-related wasting. The use of HFIAS in this study is supported by prior studies (e.g., Coates et al., 2007; Frongillo & Nanama, 2006; Knueppel, Demment, & Kaiser, 2010) that have validated the same scale with various populations in SSA. However, HFIAS, like other food insecurity scales, primarily measures previous history of food insecurity (in this case, the past 30 days or four weeks). Forward-looking measures of access to food may be needed to identify and assist individuals and households before they experience or re-experience food insecurity. Context-specific indicators to assess inadequate access to food in diverse HIV-positive populations, as well as measures that recognize subcomponents of access to food such as quality, variety, safety, and socially acceptable procurement are needed to improve construct validity.

Optimal ART adherence in this study referred to dose adherence. This definition excluded adherence pertaining to schedule or dose timing (e.g., whether ART patients took their medications in the morning or evening as prescribed). The adherence measures used in this study do not provide information on dose timing. In addition, although various thresholds based on the literature were used to define optimal ART adherence, one type of adherence measure (i.e., the 30-day VAS) had minimal variation (in both baseline and follow-up) to meaningfully

create various optimal adherence thresholds (i.e., $\geq 95\%$, $\geq 90\%$, $\geq 80\%$). For the 30-day VAS, only one optimal threshold was reported in all analyses. However, inclusion of MPR as another measure, albeit proxy, of ART adherence offset the limitations of self-reported adherence data. Although MPR (collected from pharmacy records) represented a more objective and reliable adherence measure, this dissertation was only able to collect and analyze baseline MPR. Follow-up MPR was not available during the midpoint survey because for many ART patients in the study the next pharmacy pick-up is scheduled between November 2015 and March 2016. Thus, current findings did not include the impact of *Health & Wealth* on optimal ART adherence based on follow-up MPR data. Although MPR might be a more objective measure, MPR has limitations. Regular on-time pharmacy pick-up may not necessarily mean that ART patients take their medications as prescribed. It is possible that some ART patients skip or miss doses, but show up at the pharmacy at the scheduled time to collect their medications. Pharmacy records are also susceptible to clerical error. For instance, failing to accurately record the date of pick-up (even by a few days only) might translate into suboptimal adherence.

Limitations: Program duration and qualitative data. Lastly, the overall design of the pilot study has some weaknesses. *Health & Wealth* was a pilot study with 12-month duration. The program duration may not be adequate to detect the full range and sustainability of intervention effects. Similarly, the midpoint data collection which was conducted eight months after baseline and two months after intervention training might not be enough follow-up time to reveal the full range and sustainability of effects on food security and ART adherence. Nonetheless, the endline data to be collected in March 2016 may provide some answers to sustainability and consistency of effects observed at midpoint. Although quantitative findings presented in this dissertation offer advantages and provide critical gaps in research evidence, the lack of qualitative results restricts a more descriptive and insightful interpretation of quantitative findings. A qualitative component can contextualize the study results. For instance, qualitative data – whether from individual in-depth or focus group interviews with program

participants – may expand what we know about the pathways that link food security with optimal ART adherence and confirm whether known pathways are consistent with the experiences of rural ART populations in resource-limited settings. Similarly, qualitative methods can give richer details about the individual and/or household-level mechanisms that explain why and how the intervention affected food security and ART adherence. In other words, qualitative results may provide answers to questions that are not easily verifiable with quantitative methodologies.

Conclusions

Food insecurity, defined as inadequate access to safe and nutritious food at all times, remains a global social and public health issue. Although food insecurity affects wellbeing of populations regardless of health status, PLHIV (and others with chronic health conditions) are at higher risk of food insecurity and experiencing its adverse effects. The convergence of food insecurity and HIV creates a cycle, with food insecurity increasing risk to HIV exposure and infection, and HIV in turn exacerbating vulnerability to food insecurity. On the one hand, HIV/AIDS contributes to food insecurity through loss or reduction in income, increased health expenditures, and diminished social support or safety net arrangements. On the other hand, food insecurity increases risk of HIV acquisition through its adverse effects on nutrition, mental health, and sexual risk-taking behaviors. In addition to this reciprocal link, adequate food and nutrition are important for PLHIV to improve nutritional status, boost immune system, and slow disease progression, as well as to optimize HIV therapy outcomes and minimize side effects of ARV drugs for those who are on ART.

The advancements in HIV treatment and expansion of ART coverage in SSA and other resource-limited settings have transformed HIV from a life-threatening disease to a more manageable chronic condition. However, progress has come with unintended consequences. One critical consequence is poor adherence to HIV treatment. Adherence to treatment is crucial if potential benefits of recent advancements to HIV therapy are to occur. Optimal adherence

predicts higher survival and slower disease progression. As more PLHIV get access to life-saving ARV drugs, barriers to ART adherence have been growing. Although numerous barriers to treatment adherence have been identified in the literature, food insecurity is increasingly becoming an important barrier to ART adherence. In many resource-limited communities, food-insecure ART patients skip or miss prescribed medications or doses because of perceived food requirements of HIV therapy, severe ARV drug side effects due to lack of food, and competing demands to either buy food or pay for health-related expenses.

Findings from this dissertation expands the empirical literature by providing evidence on the extent of food insecurity and its impact on ART adherence among a predominantly rural sample from Lundazi District, Eastern Province, Zambia. Consistent with previous research in SSA, the prevalence of food insecure ART patients remains high. More than 90% of the study sample experienced inadequate access to food at baseline and follow-up. In this sample of rural ART patients, food insecurity is predicted by lack of economic security in the household. In line with prior research in SSA, ART patients who earn less income, own fewer assets, and owe money are at a greater risk of food insecurity. These household economic predictors represent malleable factors that can be potentially targeted by an intervention. Furthermore, study results indicate an inverse association between food insecurity and optimal ART adherence. Consistent with a growing body of evidence from SSA, food insecure ART patients in Lundazi District are less likely to adhere to HIV treatment optimally. Findings also support an independent association between food insecurity and ART adherence. In summary, dissertation results support previous research on the prevalence and correlates of food insecurity, as well as its adverse effect on ART adherence, conducted in SSA.

Beyond examination of the prevalence and correlates of food insecurity and its effect on ART adherence in a cross-cultural and diverse geographic setting, this dissertation expands what we know about the feasibility and effects of an intervention designed to improve food security and minimize barriers to optimal ART adherence. The pilot *Health & Wealth*

intervention is an example of an integrated HIV and livelihood program. Conceptualization of *Health & Wealth* built on existing research on alterable and underlying multilevel determinants of food insecurity among PLHIV. The intervention primarily targeted the lack of adequate income and livelihood activities as upstream causes of food insecurity, which distinguishes *Health & Wealth* from prior intervention research done in Zambia that tackled downstream effects of food insecurity among PLHIV. Study findings indicate feasibility and positive impacts of the *Health & Wealth* intervention. *Health & Wealth* contributed to statistically significant improvements in food security, as well as desirable effects on optimal ART adherence. Livelihood interventions such as *Health & Wealth* offer a promising approach to address the intersecting problems of food insecurity, poverty and HIV/AIDS in resource-limited settings. However, larger experimental studies are needed to definitively establish causal impacts and program effectiveness, as well as cost-effectiveness of IHLPs and their individual components. Evidence from these larger trials may inform policy recommendations and practice guidelines to incorporate livelihood programs into HIV treatment efforts in Zambia and similar resource-limited settings.

Table 1

Strengths and limitations of food security interventions for PLHIV

Food Security Interventions						
Indicator	Food Assistance		Integrated HIV and Livelihood		Combination Food Assistance and Livelihood	
	Strength	Limitation	Strength	Limitation	Strength	Limitation
Program Design						
1. Cost-effectiveness	✓			✗		✗
2. Extraneous factors		✗		✗		✗
3. Feasibility	✓		✓		✓	
4. Household food security		✗	✓		✓	
5. Incentive	✓		✓		✓	
6. Food quality and quantity		✗	✓		✓	
7. Replicability	✓			✗		✗
8. Stability of access to food		✗	✓		✓	
9. Suitability	✓			✗	✓	
10. Sustainability of effects		✗	✓		✓	
11. Time lag of food benefits	✓			✗	✓	
Program Effectiveness						
1. Evidence-based	✓			✗		✗
2. Effect on adherence	✓			✗		✗
Potential effects beyond food security						
1. Socially acceptable way of obtaining food		✗	✓		✓	
2. Anxiety		✗	✓		✓	
3. Stigma		✗	✓		✓	
4. Other psychosocial health		✗	✓		✓	

Table 2

Data collection methods, constructs and measures

Construct	Data Collection Method	Measures and Sample Items
ART Adherence		
(a) Self-report adherence	Visual analog scale	Proportion of medication taken during the past 30 days
(b) Clinical report	Pharmacy record	Last and next prescription pick-up date, numbers of days late, proportion of missed doses
Food (In)security		
(a) Household food security	Survey	Household Food Insecurity Access Scale (Coates et al., 2007)
Covariates		
(a) Demographics	Survey	Age, gender, occupation, education level, marital status
(b) Social and economic characteristics	Survey	Household size, financial status, asset ownership, household income
(c) Health	Survey	Perceived stress, health perception, barriers to pill taking, barriers to clinic attendance, distance to health facility, travel time to health facility, transport mode for traveling to health facility
	Clinical record	Treatment regimen, treatment duration, CD4 count, weight, height

Table 3

Description and Measurement of Key Covariates

Variable	Level of Measurement	Description/Measures
Demographic		
a. Age	Continuous (interval)	Age of respondent was measured in years.
b. Gender	Categorical (binary)	Gender was coded <i>0</i> if female or <i>1</i> if male
c. Marital status	Categorical (dummy)	Marital status was coded as <i>0</i> if not married or <i>1</i> if married. <i>Not married</i> included the following categories: divorced, separated, widowed, and single.
d. Education level	Categorical (dummy)	Education level was coded as <i>0</i> if highest level of education was primary school or <i>1</i> if secondary school or postsecondary was the highest level of education.
e. Type of occupation	Categorical (dummy)	Occupation was coded as <i>0</i> if patient's occupation was farming or <i>1</i> if the occupation was non-farming. Non-farming occupation included trading, clerical, construction, managerial/professional, and service.
f. Head of household status	Categorical (binary)	Head of household status was coded as <i>0</i> if patient was not the head of household or <i>1</i> if the patient was the head of household.
g. Residence	Categorical (binary)	Residence was coded as <i>0</i> if patient was from Lundazi or <i>1</i> if patient was from Lumezi.
Social and Economic		
h. Household size	Continuous (interval)	Household size referred to the total number of household members regardless of age.
i. Financial situation	Categorical (dummy)	Financial situation referred to respondents' assessment of their financial situation during the past two years. The variable was measured originally with five response options: <i>worse</i> , <i>getting worse</i> , <i>stayed the same</i> , <i>getting better</i> , and <i>excellent</i> . The variable was recoded <i>0</i> if a respondent's financial situation either got worse or getting worse, or <i>1</i> if the financial status stayed the same, getting better or was excellent.
j. Household income	Categorical (dummy)	Household income referred to the household's average monthly income, and was measured with eight response options: 1) K0 – K 20, 2) K21 – K50, 3) K51 – K100, 4) K101 – K205, 5) K251 – K500, 6) K501 – K1,000, 7) K1,001 – K2,000, and 8) >K,2000. Based on the distribution of the variable, household income was recoded as <i>0</i> if income was between K0 –

k. Landownership	Continuous (interval)	K20, 1 if income was K21 – K50, 2 if income was K51 – K500, or 3 if income was \geq K501. Landownership measured whether respondents or their households owned land or not, and if they did, how much land in acres.
l. Ownership of transport-related assets	Continuous (interval)	Ownership of transport-related assets was a continuous variable measured by an index constructed using an approach recommended by Filmer and Pritchett (1999, 2001) and Moser and Felton (2007). ART patients were asked whether or not their households owned one or more of five transport-related assets (motor vehicle, canoe or boat, motorcycle, bicycle, and ox cart). If respondents answered yes, they were also asked to identify the number or count for each type of asset.
m. Livestock ownership	Continuous (interval)	To create each of the three asset indices (transport, livestock and household possessions), I used the equation, $A_i = (b_1 a_{1i}) + (b_2 a_{2i}) + \dots (b_k a_{ki})$, where A_i was the asset index for household “i,” $(a_{1i}, a_{2i}, \dots, a_{ki})$ were the k indicators of asset items, and (b_1, b_2, \dots, b_k) were weights used to aggregate the asset items into an index (Filmer & Pritchett, 1999, 2001). I ran principal component analysis to determine the weight for each of the asset items included in the index. A high index value indicates high level of asset ownership. Livestock ownership was a continuous variable measured by creating an asset index described in item l. ART patients were asked whether or not their households owned one or more of six types of livestock (cattle, goat, sheep, donkey, pig, and chicken). If respondents answered yes, they were also asked to identify the number or count for each type of livestock.
n. Ownership of household possessions	Continuous (interval)	Ownership of household possessions was a continuous variable measured by creating an index described in item l. ART patients were asked whether or not their households owned one or more of nine types of household possessions (radio, electric/gas stove, charcoal brazier, electric iron, charcoal iron, refrigerator, television, cellular phone, and land phone). If respondents answered yes, they were also asked to identify the number or count for each type of livestock.
o. Saving	Categorical (dummy)	Saving referred to how often respondents saved money, and was measured originally

p. Debt	Categorical (binary)	<p>with the following categories: never, sometimes, usually, and always. This variable was recoded as 0 if respondent never saved, or 1 if respondent saved sometimes or more frequently.</p> <p>Debt was a binary variable that asked respondent whether they (not their household) owed money to anyone. The variable was coded as 0 if the response was no, or 1 if the response was yes.</p>
Health/Treatment q. Health perception	Categorical (dummy)	<p>Health perception was the respondents' self-assessment of their health in general, and was measured originally with a 5-point Likert-type scale (poor, fair, good, very good, and excellent). However, this variable was recoded as 0 if the original response was poor or fair, or 1 if the original response was good, very good, or excellent.</p>
r. Perceived stress	Continuous (interval)	<p>Perceived stress referred to the degree to which respondents assessed their life situations as stressful and their ability to cope. Perceived stress was measured using the 10-item perceived stress scale (PSS; Cohen, Kamarck, & Mermelstein, 1983; Cohen & Williamson, 1988). Items on the PSS have five response options: <i>never</i> (= 0), <i>almost never</i> (= 1), <i>sometimes</i> (= 2), <i>fairly often</i> (= 3) and <i>very often</i> (= 4). Sample items include, "In the last 4 weeks, how often have you been upset because of something that happened unexpectedly" and "In the last 4 weeks, how often have you felt that things were going your way?"</p> <p>Consistent with prior research (e.g., Cohen & Williamson, 1988; Lavoie & Douglas, 2011; Leung, Lam, & Chan, 2010), I used a two-factor perceived stress scale. The first factor was a 4-item measure of perceived coping. The second factor was a 6-item measure of perceived distress. Using this factor structure, items were aggregated to obtain scores for each factor, respectively. A higher score on the perceived coping factor indicates ability to cope with stressful events. On the other hand, a higher score on the perceived distress factor suggests inability to deal with stressful situations.</p>
s. Treatment duration	Continuous (interval)	<p>Treatment duration referred to the length of time, measured in months, a patient has been</p>

		<p>taking his or her HIV treatment medications. To obtain the length of time, I calculated the number of days between a patient's medication start date and January 31, 2015 (i.e., the end of baseline data collection). The number of days was then divided by 30 to get treatment duration in months.</p>
t. Treatment regimen	Categorical (nominal/dummy)	<p>Treatment regimen referred to the ARV drugs that were prescribed to patients. Available ARV regimens in Zambia are classified into first-line or second-line. Currently, there are eight available first-line regimens in Zambia. These include, and coded originally as:</p> <ol style="list-style-type: none"> 1 = TDF 300 mg OD + FTC 200 mg OD + NVP 200 mg OD/BD 2 = TDF 300 mg OD + FTC 200 mg OD + EFV 600 mg OD 3 = AZT 300 mg BD + 3Tc 150 mg BD + NVP 200 mg OD/BD 4 = AZT 300 mg BD + 3Tc 150 mg BD + EFV 600 mg OD 5 = d4T 30 mg BD + 3TC 150 mg BD + NVP 200 mg OD/BD 6 = d4T 30 mg BD + 3TC 150 mg BD + EFV 600 mg OD 7 = ABC 300 mg BD + 3TC 150 mg BD + NVP 200 mg OD/BD 8 = ABC 300 mg BD + 3TC 150 mg BD + EFV 600 mg OD <p>Second-line regimens include:</p> <ol style="list-style-type: none"> 9 = AZT 300 mg BD + 3TC 150 mg BD + LPV/r 400/100 mg BD 10 = AZT 300 mg BD + TDF 300 mg OD + FTC 200 mg OD + LPV/r 400/100 mg BD 11 = d4T 30 mg BD + 3TC 150 mg BD + LPV/r 400/100 mg BD 12 = ABC 300 mg BD + ddI 250 mg OD + LPV/r 400/100 mg BD 13 = TDF 300 mg OD + FTC 200 mg OD + LPV/r 400/100 mg BD <p>Treatment regimen was recoded as 0 for second-line therapy or 1 for first-line therapy.</p> <p>Note: OD = Once Daily; BD = Twice Daily; mg = milligram</p>
u. Pill burden	Categorical (binary)	<p>Pill burden measured the number of pills that ART patients are required to take per day to achieve treatment efficacy. Pill burden was</p>

v. Barriers to pill taking	Continuous (interval)	<p>coded as 0 if the patient needed to take more than one pill or tablet per day, or 1 if the patient had to take only one tablet per day.²⁴ Barriers to pill taking referred to the extent to which different structural barriers to pill- or medication-taking applies to respondents' own situations. Barriers to pill taking were measured using the Structural Barriers to Medication-taking Scale (Coetzee & Kagee, 2013). The 11 items on this scale have five response options: <i>never</i> (= 0), <i>rarely</i> (= 1), <i>some of the time</i> (= 2), <i>most of the time</i> (= 3) and <i>always</i> (= 4). Sample items include, "I do not take my pills if I have to take it in front of others" and "I do not take my ART pills because traditional healing works better for me." Using this scale, items were aggregated to obtain the barrier to pill taking scores. A higher score on this scale indicates presence of substantial barriers to medication adherence.</p>
w. Barriers to clinic attendance	Continuous (interval)	<p>Barriers to clinic attendance referred to the extent to which different structural barriers to regular clinic attendance happens in respondents' lives. Barriers to clinic attendance were measured using the Structural Barriers to Clinic Attendance Scale (Coetzee & Kagee, 2013). The 12 items on this scale have five response options: <i>never</i> (= 0), <i>rarely</i> (= 1), <i>some of the time</i> (= 2), <i>most of the time</i> (= 3) and <i>always</i> (= 4). Sample items include, "I do not want to be identified as HIV positive" and "The staff at the clinic is impatient towards me." Using this scale, items were aggregated to obtain the barrier to clinic attendance scores. A higher score on this scale indicates frequent presence of structural barriers to regular clinic attendance.</p>
x. Distance to health facility	Continuous (interval)	<p>Distance to health facility measured the approximate distance (in kilometers) between respondents' home and the health facility.</p>
y. Travel time to health facility	Continuous (interval)	<p>Travel time to health facility measured the approximate time (in minutes) that it takes respondents to travel from their homes to the health facility.</p>

²⁴ Of the ARV prescriptions, Atripla (TDF + FTC + EFV) is the only all-in-one combination tablet that is prescribed currently to ART patients in Zambia. All other ARV regimens require patients to take more than one pill a day. There are other all-in-one combination tablets that are available elsewhere, including in the United States. Examples include Complera or Eviplera (a combination of rilpivirine, tenofovir, and emtricitabine); Stribild (a combination of elvitegravir, cobicistat, tenofovir, and emtricitabine), and Trumeq (dolutegravir, abacavir, and lamivudine).

Table 4

Descriptive Statistics and Bivariate Analysis Results

Variables ¹	Food Insecurity		ART Adherence			
	% or <i>M</i> (<i>SD</i>)	Mean Score or β [95% Confidence Interval]	Proportion of Optimally Adherent Patients or β /OR (SE) [95% Confidence Interval]			
			Baseline VAS		Baseline MPR \geq 95%	
			Adherent	Non- adherent	Adherent	Non- adherent
<i>Outcome Variables</i>						
Household food insecurity (baseline)						
Food insecurity (continuous)	14.43 (7.86)	-	0.99 (0.03)	[0.93, 1.05]	0.98 (0.03)	[0.93, 1.03]
Food insecurity (categorical)						
Food secure	7%	-	86%	14%	86%	14%
Mildly food insecure	2%	-	100%	0%	100%	0%
Moderately food insecure	17%	-	71%	29%	69%	31%
Severely food insecure	74%	-	74%	26%	65%	35%
Household food insecurity (follow-up)						
Food insecurity (continuous)	11.34 (6.46)	-				
Food insecurity (categorical)						
Food secure	5%	-	100%	0%	-	-
Mildly food insecure	11%	-	89%	11%	-	-
Moderately food insecure	14%	-	100%	0%	-	-
Severely food insecure	70%	-	89%	11%	-	-
ART adherence						
30-day visual analog scale (baseline)		-				
Adherent (\geq 95%)	74%	14.63 [12.63, 16.63]	-	-	-	-
Nonadherent (< 95%)	26%	15.45 [12.07, 18.84]	-	-	-	-
30-day visual analog scale (follow-up)						
Adherent (\geq 95%)	91%	11.03 [9.55, 12.50]	-	-	-	-
Nonadherent (< 95%)	9%	14.57 [7.51, 21.63]	-	-	-	-

Medication possession ratio (baseline)						
Adherent ($\geq 95\%$)	67%	13.91 [11.97, 15.85]	-	-	-	-
Nonadherent ($< 95\%$)	33%	15.41 [12.56, 18.26]	-	-	-	-
Adherent ($\geq 90\%$)	71%	13.79 [11.93, 15.65]	-	-	-	-
Nonadherent ($< 90\%$)	29%	15.93 [12.81, 19.04]	-	-	-	-
Adherent ($\geq 80\%$)	77%	13.99 [12.18, 15.79]	-	-	-	-
Nonadherent ($< 80\%$)	23%	15.74 [12.52, 19.23]	-	-	-	-
<i>Demographics</i>						
Age (in years)	37.54 (7.39)	-0.15 [-0.35, 0.06]	1.00 (0.03)	[0.94, 1.06]	1.02 (0.03)	[0.96, 1.07]
Age						
<40 years old	54%	15.58 [13.35, 17.81]	75%	25%	68%	32%
≥ 40 years old	46%	13.04 [10.91, 15.18]	76%	24%	67%	33%
Gender						
Female	56%	16.04 [13.96, 18.11]*	77%	23%	68%	32%
Male	44%	12.34 [10.06, 14.62]	72%	28%	67%	33%
Marital status						
Married	75%	13.82 [12.07, 15.57]	73%	27%	68%	32%
Not married	25%	16.28 [12.85, 19.71]	80%	20%	68%	32%
Education level						
Primary education	65%	16.22 [14.17, 17.80]*	78%	22%	72%	28%
Secondary education or higher	35%	11.03 [8.26, 13.80]	70%	30%	59%	41%
Type of Occupation						
Farming	75%	15.24 [13.60, 16.87]	75%	25%	64%	36%
Non-farming	25%	11.96 [8.08, 15.84]	75%	25%	80%	20%
Head of household						
Yes	35%	13.86 [11.87, 15.86]	75%	25%	65%	35%
No	65%	15.49 [12.96, 18.01]	75%	25%	74%	26%
Residence						
Lumezi	50%	15.32 [13.20, 17.44]	72%	28%	57%*	43%
Lundazi	50%	13.55 [11.24, 15.85]	78%	22%	78%	22%

Social and Economic Characteristics

Household size						
Five or less	47%	14.66 [12.07, 17.25]	76%	24%	67%	33%
More than five members	53%	14.22 [12.31, 16.13]	74%	26%	68%	32%
Household size (continuous)	5.99 (3.60)	-0.43 [-0.78, -0.08]*	0.97 (0.07)	[0.84, 1.12]	0.99 (0.06)	[0.87, 1.12]
Financial situation						
Worse than two years ago	82%	16.04 [14.42, 17.65]*	74%	26%	67%	33%
Stayed the same or better	18%	7.00 [4.39, 9.61]	80%	20%	71%	29%
Household income						
K0 – K20 (< \$0.15 per day)	45%	17.09 [14.90, 19.27]*	80%	20%	62%	38%
K21 – K50 (\$0.15 - \$0.30 per day)	25%	16.04 [13.11, 18.97]	65%	35%	75%	25%
K51 – K500 (\$0.30 - \$2.75 per day)	15%	12.07 [8.15, 15.98]	64%	36%	67%	33%
≥K501 (> \$2.75 per day)	15%	5.93 [3.51, 8.36]	86%	14%	73%	27%
Landownership						
Do not own	11%	12.18 [4.61, 19.76]	91%	9%	91%	9%
Own	89%	14.70 [13.16, 16.24]	73%	27%	65%	35%
Land (in acreage)	3.80 (3.98)	-0.40 [-0.71, -0.10]*	1.02 (0.06)	[0.91, 1.13]	0.96 (0.05)	[0.87, 1.06]
Transportation asset						
≤ Median value	77%	15.49 [13.70, 17.28]*	80%*	20%	69%	31%
> Median value	23%	10.83 [8.01, 13.64]	58%	42%	64%	36%
Transportation asset index	0.19 (0.38)	-5.30 [-8.21, -2.38]*	0.42 (0.27)	[0.12, 1.48]	0.78 (0.44)	[0.27, 2.34]
Livestock ownership						
≤ Median value	48%	15.19 [12.86, 17.52]	77%	23%	73%	27%
> Median value	52%	13.74 [11.61, 15.86]	74%	26%	63%	37%
Livestock ownership index	1.40 (2.99)	-0.64 [-0.97, -0.31]*	0.99 (0.07)	[0.87, 1.13]	0.95 (0.06)	[0.84, 1.08]
Household possessions						
≤ Median value	36%	15.58 [13.44, 17.73]	76%	24%	69%	31%
> Median value	64%	13.78 [11.66, 15.91]	75%	25%	67%	33%
Household possessions index	0.64 (0.81)	-4.32 [-5.54, -3.10]*	1.21 (0.33)	[0.71, 2.08]	1.10 (0.29)	[0.66, 1.83]
Respondent saves money...						
Never	36%	13.28 [11.08, 15.48]*	69%	31%	61%	39%
Sometimes	50%	16.29 [14.02, 18.55]	82%	18%	70%	30%
Usually or Always	14%	9.93 [4.66, 15.20]	69%	31%	71%	29%
Respondent owes money...						
Yes	24%	15.25 [11.95, 18.55]	78%	22%	58%	42%
No	76%	14.17 [12.38, 15.96]	74%	26%	71%	29%

<i>Health Characteristics</i>						
ART treatment duration						
≤ Median value (19 months)	50%	14.78 [12.57, 16.99]	78%	22%	73%	27%
> Median value (19 months)	50%	14.08 [11.83, 16.33]	72%	28%	62%	38%
ART treatment duration (in months)	26.40 (20.66)	-0.01 [-0.08, 0.07]	1.00 (0.01)	[0.98, 1.02]	0.97 (0.01)	[0.95, 0.99]*
Health perception						
Fair/Poor	19%	18.58 [15.07, 22.09]*	65%	35%	50%	50%
Good/Very Good/Excellent	81%	13.46 [11.77, 15.16]	78%	22%	72%	28%
Perceived stress (coping, continuous)	9.44 (4.24)	-0.13 [-0.50, 0.24]	0.97 (0.05)	[0.87, 1.09]	1.01 (0.05)	[0.91, 1.11]
Perceived stress (coping, categorical)						
≤ Median score	53%	15.51 [13.07, 17.95]	75%	25%	69%	31%
> Median score	47%	13.04 [11.16, 14.92]	75%	25%	65%	35%
Perceived stress (distress, continuous)	7.45 (4.64)	0.72 [0.41, 1.03]*	0.99 (0.05)	[0.89, 1.10]	1.03 (0.05)	[0.94, 1.12]
Perceived stress (distress, categorical)						
≤ Median score	53%	10.96 [9.24, 12.69]*	74%	26%	65%	35%
> Median score	47%	18.40 [16.17, 20.64]	77%	23%	70%	30%
Treatment regimen						
First-line ²						
TDF 300 mg OD + FTC 200 mg OD + EFV 600 mg OD	97%	14.54 [12.96, 16.13]	74%	26%	67%	33%
AZT 300 mg BD + 3Tc 150 mg BD + NVP 200 mg OD/BD	78%					
ABC 300 mg BD + 3TC 150 mg BD + NVP 200 mg OD/BD	8%					
ABC 300 mg BD + 3TC 150 mg BD + EFV 600 mg OD	7%					
Second-line	4%					
AZT 300 mg BD + 3TC 150 mg BD + LPV/r 400/100 mg BD	3%	10.67 [3.01, 24.35]	100%	0%	67%	33%
TDF 300 mg OD + FTC 200 mg OD + LPV/r 400/100 mg BD	2%					
Pill burden	1%					
One pill a day	78%	14.24 [12.42, 16.06]	74%	26%	70%	30%
More than one pill a day	22%	15.09 [12.02, 18.16]	79%	21%	59%	41%
CD4 count						
< 500 cells/mm ³	61%	15.07 [12.85, 17.28]	73%	27%	68%	32%

≥ 500 cells/ mm ³	39%	14.14 [11.86, 16.41]	79%	21%	68%	32%
CD4 count (interval)	471.27 (293.56)	-0.001 [-0.01, 0.004]	1.42 (0.75)	[0.05, 4.02]	0.96 (0.44)	[0.39, 2.34]
Body mass index						
Underweight	6%	20.17 [12.41, 27.92]	50%	50%	67%	33%
Normal weight	94%	14.43 [12.80, 16.05]	75%	25%	66%	34%
Body mass index (interval) ²	21.91 (2.69)	-0.08 [-0.68, 0.52]	0.94 (0.09)	[0.78, 1.13]	0.94 (0.08)	[0.80, 1.11]
Barriers to pill taking						
≤ Median score	69%	13.26 [11.39, 15.13]*	78%	22%	66%	34%
> Median score	31%	17.06 [14.37, 19.76]	69%	31%	71%	29%
Barriers to pill taking (continuous)	3.00 (7.67)	2.99 [1.48, 4.50]*	0.97 (0.03)	[0.92, 1.02]	1.03 (0.03)	[0.98, 1.09]
Barriers to clinic attendance						
≤ Median score	70%	13.56 [11.70, 15.42]	73%	27%	69%	31%
> Median score	30%	16.13 [13.24, 19.02]	79%	21%	63%	37%
Barriers to clinic attendance	5.30 (9.72)	5.30 [3.37, 7.23]*	1.01 (0.03)	[0.96, 1.07]	0.99 (0.02)	[0.95, 1.03]
Distance to health facility						
≤ Median value (8 kilometers)	54%	14.24 [12.04, 16.43]	74%	26%	74%	26%
> Median value (8 kilometers)	46%	14.65 [12.39, 16.91]	77%	23%	60%	40%
Distance to health facility (in kilometers)	11.42 (12.28)	0.42 [-2.69, 3.53]	0.99 (0.02)	[0.95, 1.03]	0.94 (0.02)	[0.90, 0.99]*
Travel time to health facility						
≤ Median value (90 minutes)	59%	14.02 [11.82, 16.22]	75%	25%	64%	36%
> Median value (90 minutes)	41%	15.02 [12.87, 17.18]	75%	25%	73%	27%
Travel time to health facility (in minutes)	110.19 (97.74)	1.01 [-2.03, 4.05]	1.00 (0.00)	[0.99, 1.01]	1.00 (0.00)	[1.00, 1.01]

* $p < .05$, two-tailed test. All results were based on baseline data unless noted otherwise.

¹ Univariate statistics were based on complete case analysis. All bivariate tests were also conducted using complete case analysis.

² OD = Once a Day; BD = Twice a Day; mg = milligram.

Notes: % = percentage distribution for categorical variables; M (SD) = mean (standard deviation) for continuous variables; Proportion of optimally adherent patients for categorical variables; β (SE) [95% Confidence Interval] for continuous variables; SE = Standard error

Table 5

Baseline Characteristics of Treatment and Comparison Participants

Variables	% or <i>M</i> (SD)		<i>P</i> value
	Lumezi	Lundazi	
Food insecurity			
Household food insecurity			
Food insecurity (continuous)	15.32 (1.06)	13.55 (1.15)	0.26
Food insecurity (categorical)			0.72
Food secure	6%	8%	
Food insecure	94%	92%	
ART adherence			
30-day visual analog scale			0.50
Optimally adherent (=100%)	72%	78%	
Nonadherent (< 100%)	28%	22%	
Medication possession ratio			0.03
Optimally adherent (≥95%)	57%	78%	
Nonadherent (< 95%)	43%	22%	
Optimally adherent (≥90%)	57%	86%	0.00
Nonadherent (< 90%)	43%	14%	
Optimally adherent (≥80%)	63%	90%	0.00
Nonadherent (< 80%)	37%	10%	
<i>Demographics</i>			
Age (in years)	37.62 (7.19)	37.47 (7.65)	0.92
Gender			0.37
Female	52%	61%	
Male	48%	39%	
Marital status			0.45
Married	72%	78%	
Not married	28%	22%	
Education level			0.89
Primary education	66%	65%	
Secondary education or higher	34%	35%	
Type of Occupation			0.00
Farming	98%	53%	
Non-farming	2%	47%	
Head of household			0.58
Yes	68%	63%	
No	32%	37%	
<i>Social and Economic Characteristics</i>			
Household size (continuous)	6.04 (2.63)	5.94 (4.38)	0.89

Financial situation			0.04
Worse than two years ago	90%	75%	
Stayed the same or better	10%	25%	
Household income			0.00
K0 – K20 (< \$0.15 per day)	62%	29%	
K21 – K50 (\$0.15 - \$0.30 per day)	32%	18%	
K51 – K500	6%	24%	
(\$0.30 - \$2.75 per day)			
≥K501 (> \$2.75 per day)	0%	29%	
Land (in acreage)	3.2 (2.29)	4.39 (5.08)	0.13
Transportation asset index	0.09 (0.24)	0.29 (0.46)	0.01
Livestock ownership index	0.89 (1.68)	1.84 (3.83)	0.11
Household possessions index	0.34 (0.34)	0.94 (1.01)	0.00
Respondent saves money...			0.00
Never	64%	8%	
Sometimes	30%	69%	
Usually or Always	6%	23%	
Respondent owes money...			0.02
Yes	14%	33%	
No	86%	67%	
<i>Health Characteristics</i>			
ART treatment duration (in months)	35.50 (23.43)	17.49 (12.33)	0.00
Health perception			0.22
Fair/Poor	14%	24%	
Good/Very Good/Excellent	86%	76%	
Perceived stress scale (coping)	11.55 (4.36)	7.41 (2.95)	0.00
Perceived stress scale (distress)	5.36 (4.32)	9.49 (4.01)	0.01
Treatment regimen			0.57
First-line	98%	96%	
Second-line	2%	4%	
Pill burden			0.00
One pill a day	62%	90%	
More than one pill a day	38%	10%	
Body mass index	21.83 (2.77)	22.00 (2.62)	0.76
CD4 count	523.13 (347.33)	419.42 (219.22)	0.08
Barriers to pill taking	1.32 (3.49)	4.63 (10.03)	0.03
Barriers to clinic attendance	3.88 (9.18)	6.67 (10.12)	0.06
Distance to health facility (in kilometers)	15.29 (14.91)	7.64 (7.35)	0.00
Travel time to health facility (in minutes)	127.74 (86.18)	92.98 (105.90)	0.07

Note: % = percentage distribution for categorical variables; *M* = mean for continuous variables. *P* values based on two-tailed tests.

Table 6

Proportion of Sample and their Households Experiencing Various Food Insecurity-Related Conditions and Frequency of Experiencing Food Insecurity Conditions at Baseline and Follow-up

	Food-Insecurity Condition	N	Baseline				Follow-Up			
			Never	Rarely	Sometimes	Often	Never	Rarely	Sometimes	Often
200	<i>During the past four weeks how often did you or household member...</i>									
	1. Worry that the household would not have enough food?	101	17%	18%	28%	37%				
		80	18%	16%	26%	40%	16%	33%	36%	15%
	2. Not able to eat the kinds of foods you preferred because of a lack of resources?	101	12%	25%	23%	40%				
		80	11%	20%	25%	44%	16%	32%	31%	21%
	3. Eat a limited variety of foods due to a lack of resources?	101	14%	19%	25%	41%				
		80	14%	17%	23%	46%	14%	26%	34%	26%
	4. Eat some foods that you really did not want to eat because of a lack of resources to obtain other types of food?	101	14%	21%	24%	41%				
		80	12%	18%	24%	46%	19%	40%	21%	20%
	5. Eat a smaller meal than needed because there was not enough food?	101	14%	23%	23%	40%				
		80	16%	19%	21%	44%	29%	21%	35%	15%
	6. Eat fewer meals in a day because there was not enough food?	101	19%	19%	20%	42%				
		80	19%	16%	19%	46%	26%	19%	33%	22%
	7. Did not have food to eat of any kind in the household because of lack of resources to get food?	101	36%	25%	14%	25%				
		80	36%	24%	11%	29%	44%	26%	24%	6%
	8. Go to sleep at night hungry because there was not enough food?	101	47%	27%	15%	11%				
		80	45%	26%	18%	11%	50%	21%	24%	5%
	9. Spend a whole day and night without eating anything because there was not enough food?	101	50%	23%	19%	8%				
		80	51%	21%	19%	9%	75%	8%	12%	5%

Table 7

Linear regression results of household food insecurity and ART patient characteristics with estimates on coefficient and respective standard error and confidence interval (CI 95%) based on multiply imputed data

Variables	Household Food Insecurity Access Scale Score							
	Model 1		Model 2		Model 3		Model 4	
	β (Robust SE)	95% CI	β (Robust SE)	95% CI	β (Robust SE)	95% CI	β (Robust SE)	95% CI
Demographic								
Age (in years)	-0.13 (0.11)	[-0.35, 0.09]	-0.15 (0.10)	[-0.35, 0.05]	-0.06 (0.09)	[-0.25, 0.13]		
Gender (reference is female)	-2.67 (1.95)	[-6.55, 1.21]	0.17 (1.93)	[-3.68, 4.02]	-0.15 (1.56)	[-3.25, 2.96]		
Marital status (reference is not married)	-1.04 (1.87)	[-4.74, 2.67]	-0.50 (1.78)	[-4.03, 3.02]	-0.17 (1.43)	[-2.67, 3.01]		
Education level (reference is primary education)	-4.63 (1.71)**	[-8.02, -1.23]	-0.80 (1.76)	[-4.29, 2.70]	-0.82 (1.54)	[-3.88, 2.25]		
Type of occupation (reference is farming)	-1.30 (2.35)	[-5.97, 3.36]	2.22 (2.12)	[-2.01, 6.44]	2.53 (2.11)	[-1.66, 6.73]		
Head of household status (reference is non-head of household)	0.95 (2.13)	[-3.27, 5.18]	-0.24 (2.11)	[-4.44, 3.96]	0.23 (1.66)	[-3.08, 3.53]		
Residence (reference is Lundazi)	1.26 (1.87)	[-2.46, 4.98]	-0.02 (1.91)	[-3.82, 3.78]	2.24 (1.94)	[-1.62, 6.10]	1.79 (1.35)	[-0.89, 4.47]
Social and Economic								
Household size			-0.23 (0.23)	[-0.69, 0.24]	-0.20 (0.18)	[-0.57, 0.16]	-0.30 (0.17) [†]	[-0.64, 0.05]
Financial situation (reference is worse than two years ago)			-3.39 (1.68)*	[-6.74, 0.03]	-2.73 (1.83)	[-6.37, 0.91]	-3.12 (1.60) [†]	[-6.31, 0.07]
Household income (reference is K0 – K20 per month)								

	K21 – K50 per month	0.33 (1.50)	[-2.66, 3.31]	-0.12 (1.23)	[-2.58, 2.33]	0.21 (1.21)	[-2.19, 2.61]
	K51 – K500 per month	-5.54 (2.67)*	[-10.85, - 0.23]	-4.88 (2.59) [†]	[-10.04, 0.28]	-5.13 (2.27)*	[-9.65, -0.62]
	≥ K501 per month	-8.81 (2.89)**	[-14.57, - 3.05]	-4.88 (3.17)	[-11.20, 1.43]	-5.24 (2.76) [†]	[-10.72, 0.23]
	Transportation asset index	-2.06 (2.22)	[-6.48, 2.36]	-1.94 (2.15)	[-6.22, 2.34]	-2.81 (1.63) [†]	[-6.05, 0.44]
	Household possessions index	-1.92 (1.30)	[-4.52, 0.67]	-3.31 (1.18)**	[-5.66, -0.97]	-2.74 (0.89)**	[-4.51, -0.98]
	Livestock ownership index	-0.02 (0.30)	[-0.62, 0.57]	-0.16 (0.27)	[-0.70, 0.38]		
	Landownership (in acreage)	0.04 (0.19)	[-0.33, 0.41]	-0.00 (0.17)	[-0.34, 0.33]		
	Saving behavior (reference is do not save)	4.16 (2.03)*	[0.12, 8.20]	-1.08 (1.86)	[-4.78, 2.63]		
	Debt (reference is no debt)	3.40 (1.75) [†]	[-0.09, 6.89]	3.20 (1.80) [†]	[-0.40, 6.79]	3.16 (1.52)*	[0.14, 6.19]
202	Health						
	Perceived stress, distress			0.59 (0.21)**	[0.18, 1.01]	0.59 (0.18)**	[0.23, 0.96]
	Perceived stress, coping			-0.53 (0.19)**	[-0.91, -0.14]	-0.51 (0.17)**	[-0.85, -0.17]
	Health perception (reference is poor/fair)			-1.76 (1.61)	[-4.97, 1.45]		
	ART treatment duration (in months)			0.02 (0.03)	[-0.04, 0.08]		
	N	101					
	Number of Imputations	20					
	Constant	21.91***	22.37***	22.38***		19.29***	
	R ²	0.1699	0.4715	0.6050		0.5850	
	Adjusted R ²	0.1075	0.3555	0.4936		0.5337	

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test.

Note: robust SE = robust standard error. R^2 and adjusted R^2 were calculated for multiple imputation models (Harel, 2009).

Table 8

Logistic regression analysis of baseline ART adherence, food insecurity and ART patient characteristics with estimates on coefficient and respective standard error and confidence interval (CI 95%) using multiply imputed data

Variables	ART Adherence							
	30-day VAS		MPR ≥95%		MPR ≥90%		MPR ≥80%	
	OR (Robust SE)	95% CI	OR (Robust SE)	95% CI	OR (Robust SE)	95% CI	OR (Robust SE)	95% CI
Key explanatory variable								
Food insecurity, continuous	1.00 (0.04)	[0.93, 1.07]	0.93 (0.05)	[0.85, 1.03]	0.93 (0.05)	[0.84, 1.03]	0.95 (0.05)	[0.85, 1.05]
Covariates								
Education level (reference is primary education)			0.36 (0.22) [†]	[0.11, 1.19]	0.37 (0.25)	[0.09, 1.42]	0.54 (0.38)	[0.14, 2.13]
Type of occupation (reference is farming)	0.32 (0.25)	[0.07, 1.49]						
Residence (reference is Lundazi)	0.20 (0.15) [*]	[0.05, 0.84]						
Financial situation (reference is worse than two years ago)			0.27 (0.36)	[0.02, 3.68]	0.45 (0.75)	[0.02, 11.97]	0.31 (0.56)	[0.01, 10.80]
Household income			1.52 (0.55)	[0.75, 3.10]	1.53 (0.72)	[0.61, 3.85]	1.56 (0.82)	[0.56, 4.38]
Transportation asset index	0.11 (0.09) ^{**}	[0.02, 0.56]	0.28 (0.26)	[0.05, 1.69]	0.32 (0.35)	[0.04, 2.78]	0.34 (0.41)	[0.03, 3.61]
Livestock ownership index	1.20 (0.13) [†]	[0.97, 1.47]						
Debt (reference is no debt)			0.31 (0.20) [†]	[0.09, 1.07]	0.39 (0.24)	[0.12, 1.30]	0.50 (0.33)	[.014, 1.81]
Health perception	2.05 (0.65) [*]	[1.10, 3.82]						
Perceived stress, distress			1.13 (0.09)	[0.97, 1.32]	1.14 (0.10)	[0.97, 1.35]	1.08 (0.10)	[0.91, 1.29]

Perceived stress, coping	1.08 (0.10)	[0.91, 1.29]	1.06 (0.11)	[0.86, 1.29]	1.00 (0.11)	[0.80, 1.23]
ART treatment duration (in months)	0.98 (0.01)	[0.96, 1.01]	0.98 (0.01) [†]	[0.95, 1.00]	0.98 (0.01)	[0.95, 1.01]
Distance to health facility	0.92 (0.04) [†]	[0.84, 1.00]	0.92 (0.04) [†]	[0.83, 1.00]	0.93 (0.05)	[0.84, 1.02]
Time to travel to health facility	1.01 (0.00)*	[1.00, 1.02]	1.01 (0.00)	[1.00, 1.02]	1.01 (0.01)	[1.00, 1.02]
Number of Imputations						20
<i>N</i>						101

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test.

Note: robust SE = robust standard error.

Logistic regression analysis of baseline ART adherence and alternative specifications of food insecurity with estimates on coefficient and respective standard error and confidence interval (CI 95%) using multiply imputed data¹

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¹ Only the coefficient estimates for the main explanatory variable (food insecurity) are presented in this table. However, results were based on multivariable logistic regression models which included the same covariates in Table 8.

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test. Note: robust SE = robust standard error.

Table 10

Differences in Outcomes Before and After Adjustment of Sample Selection based on Multiply Imputed Data (m = 20)

Group and Comparison	Outcome Measures	
	Food Insecurity	Optimal ART Adherence ⁴
Unadjusted mean difference (robust <i>SE</i>)	-3.23 (1.61)*	
Adjusted mean difference (robust <i>SE</i>) ¹	-3.77 (1.59)*	
Regression-adjusted mean difference (robust <i>SE</i>) ²	-5.76 (2.00)**	
Adjusted mean difference controlling for sample selection using ML procedure (robust <i>SE</i>) ³	-5.65 (2.63)*	
Adjusted mean difference controlling for sample selection using two-step procedure (<i>SE</i>) ³	-5.49 (2.52)*	
Unadjusted odds ratio (robust <i>SE</i>)		1.03 (0.63)
Adjusted odds ratio (robust <i>SE</i>) ¹		1.12 (0.69)
Regression-adjusted mean difference (robust <i>SE</i>) ²		1.19 (1.08)

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test.

Note: *SE* = standard error. Reference group = Control group

¹ Results were adjusted for baseline value of the outcome variable.

² Results were adjusted for covariates of the outcome variable. Covariates for each outcome measure were based on the multivariable models in Tables 7 and 8.

³ Results were adjusted for the sample selection process and covariates of the outcome variable (Table 12).

⁴ For optimal ART adherence, adjusted mean differences based on treatment effect models were not estimated. In Stata, application of the treatment effect model after multiple imputations of missing data is currently not available for binary outcome variables.

Table 11

Effects of Health & Wealth on Food Insecurity and Optimal ART Adherence After Covariate Adjustment using Linear and Logistic Regression based on Multiply Imputed Data (m = 20)

Variables	Outcome Measures	
	Food Insecurity	Optimal ART Adherence ²
	β (Robust SE)	OR (Robust SE)
Treatment (reference is control)	-5.76 (2.00)**	1.19 (1.08)
<i>Covariates of Outcome Variables</i>		
<i>Demographics</i>		
Age (in years)		
Type of occupation (reference is farming)		1.41 (1.44)
<i>Social and Economic</i>		
Household size	-0.25 (0.26)	
Financial situation (reference is worse than two years ago)	-5.11 (2.94) [†]	
Household income (reference is K0 – K20 per month)		
K21 – K50 per month	3.45 (1.93) [†]	
K51 – K500 per month	2.17 (2.31)	
≥ K501 per month	2.40 (5.11)	
Transportation asset index	-1.71 (1.92)	0.75 (0.82)
Household possessions index	-1.23 (1.80)	
Livestock ownership index		1.15 (0.18)
Landownership (in acreage)		
Saving behavior (reference is do not save)		
Debt (reference is no debt)	-0.28 (1.95)	
Food insecurity	0.08 (0.13)	1.01 (0.04)
<i>Health</i>		
Perceived stress, distress	0.37 (0.27)	
Perceived stress, coping	0.64 (0.26)*	
Health perception (reference is poor/fair)		2.08 (1.63)
ART treatment duration (in months)		
Optimal ART adherence (reference is suboptimal adherence) ¹		1.90 (1.62)

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test.

Note: β = coefficient; OR = odds ratio; robust SE = robust standard error.

¹ Baseline optimal ART adherence was measured using a 30-day visual analog scale.

² Optimal ART adherence at follow-up was also measured using a 30-day visual analog scale.

Table 12

Effects of Health & Wealth on Food Security after Adjustment of Sample Selection (MLE) based on Multiply Imputed Data (m = 20)

<i>Variables</i>	Food Insecurity
	β (Robust SE)
Treatment (reference is control)	-5.65 (2.63)*
<i>Covariates of Outcome Variables</i>	
Household size	-0.25 (0.26)
Financial situation (reference is worse than two years ago)	-5.10 (2.86) [†]
Household income (reference is K0 – K20 per month)	
K21 – K50 per month	3.48 (1.89) [†]
K51 – K500 per month	2.16 (2.22)
≥ K501 per month	2.41 (4.98)
Transportation asset index	-1.69 (1.76)
Household possessions index	-1.21 (1.80)
Debt (reference is no debt)	-0.25 (1.85)
Baseline food insecurity	0.07 (0.13)
Perceived stress, distress	0.38 (0.26)
Perceived stress, coping	0.64 (0.27)*
<i>Sample Selection Variables</i>	
Gender (reference is male)	0.64 (0.40)
Education level (reference is primary education)	0.67 (0.42)
Transportation index	-1.25 (0.60)*
Household possessions index	-2.58 (0.56)***
Livestock ownership index	0.12 (0.09)
Landownership (reference is do not own land)	-0.78 (0.64)
Optimal ART adherence (reference is suboptimal adherence) ³	-0.89 (0.37)*
CD4 count (reference is low CD4 count)	0.05 (0.55)
ART treatment duration (reference is 19 months or shorter)	2.21 (0.42)***

¹ For optimal ART adherence, effect of Health & *Wealth* on optimal ART adherence after adjustment of sample selection was not estimated. In Stata, application of the treatment effect model after multiple imputations of missing data is currently not available for binary outcome variables.

Table 13

Comparison of Outcomes Before and After Adjustment of Sample Selection Based on Number of Multiply Imputed Dataset

<i>Group and Comparison</i>	<i>Outcome Measures</i>	
	<i>Food Insecurity</i>	<i>ART Adherence⁵</i>
<i>m</i> = 20		
Unadjusted mean difference (robust <i>SE</i>)	-3.23 (1.61)*	
Adjusted mean difference (robust <i>SE</i>) ¹	-3.77 (1.59)*	
Regression-adjusted mean difference (robust <i>SE</i>) ²	-5.76 (2.00)**	
Adjusted mean difference controlling for sample selection using ML procedure (robust <i>SE</i>) ³	-5.65 (2.63)*	
Adjusted mean difference controlling for sample selection using ML procedure using two-step procedure (<i>SE</i>) ³	-5.49 (2.52)*	
Unadjusted odds ratio (robust <i>SE</i>)		1.03 (0.63)
Adjusted odds ratio (robust <i>SE</i>) ¹		1.12 (0.69)
Regression-adjusted odds ratio (robust <i>SE</i>) ²		1.19 (1.08)
<i>m</i> = 5		
Unadjusted mean difference	-3.80 (1.37)**	
Adjusted mean (Robust <i>SE</i>) difference ¹	-4.41 (1.29)**	
Regression-adjusted mean (Robust <i>SE</i>) difference ²	-6.59 (1.72)***	
Adjusted mean (Robust <i>SE</i>) difference controlling for sample selection using ML procedure ³	-6.81 (2.04)**	
Adjusted mean (<i>SE</i>) difference controlling for sample selection using ML procedure using two-step procedure ³	-6.79 (2.01)**	
Unadjusted odds ratio (robust <i>SE</i>)		1.00 (0.62)
Adjusted odds ratio (robust <i>SE</i>) ¹		1.13 (0.74)
Regression-adjusted odds ratio (robust <i>SE</i>) ²		1.12 (1.16)
<i>m</i> = 50		
Unadjusted mean difference	-3.33 (1.56)*	
Adjusted mean (Robust <i>SE</i>) difference ¹	-3.91 (1.53)*	
Regression-adjusted mean (Robust <i>SE</i>) difference ²	-6.07 (2.15)**	
Adjusted mean (Robust <i>SE</i>) difference controlling for sample selection using ML procedure ³	-5.86 (2.64)*	
Adjusted mean (<i>SE</i>) difference controlling for sample selection using ML procedure using two-step procedure ⁴	-5.88 (2.54)*	
Unadjusted odds ratio (robust <i>SE</i>)		0.99 (0.61)
Adjusted odds ratio (robust <i>SE</i>) ¹		1.07 (0.67)
Regression-adjusted odds ratio (robust <i>SE</i>) ²		1.05 (0.97)
<i>m</i> = 100		
Unadjusted mean difference	-3.34 (1.61)*	
Adjusted mean (Robust <i>SE</i>) difference ¹	-3.90 (1.45)**	

Regression-adjusted mean (Robust <i>SE</i>) difference ²	-5.76 (1.97)**
Adjusted mean (Robust <i>SE</i>) difference controlling for sample selection using ML procedure ³	-5.72 (2.45)*
Adjusted mean (<i>SE</i>) difference controlling for sample selection using ML procedure using two-step procedure ³	-5.70 (2.33)*
Unadjusted odds ratio (robust <i>SE</i>)	1.01 (0.61)
Adjusted odds ratio (robust <i>SE</i>) ¹	1.09 (0.68)
Regression-adjusted odds ratio (robust <i>SE</i>) ³	1.01 (0.99)

† $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test.

Note: ML = maximum likelihood; robust SE = robust standard error. Reference group was the control group.

¹ Results were adjusted for baseline value of the outcome variable.

² Results were adjusted for covariates of the outcome variable. Covariates for each outcome measure were based on the multivariable models in Tables 7 and 8.

³ Results were adjusted for the sample selection process and covariates of the outcome variable (Table 12).

⁵ For optimal ART adherence, adjusted mean differences based on treatment effect models were not estimated. In Stata, application of the treatment effect model after multiple imputations of missing data was not available for binary outcomes at the time of writing this dissertation.

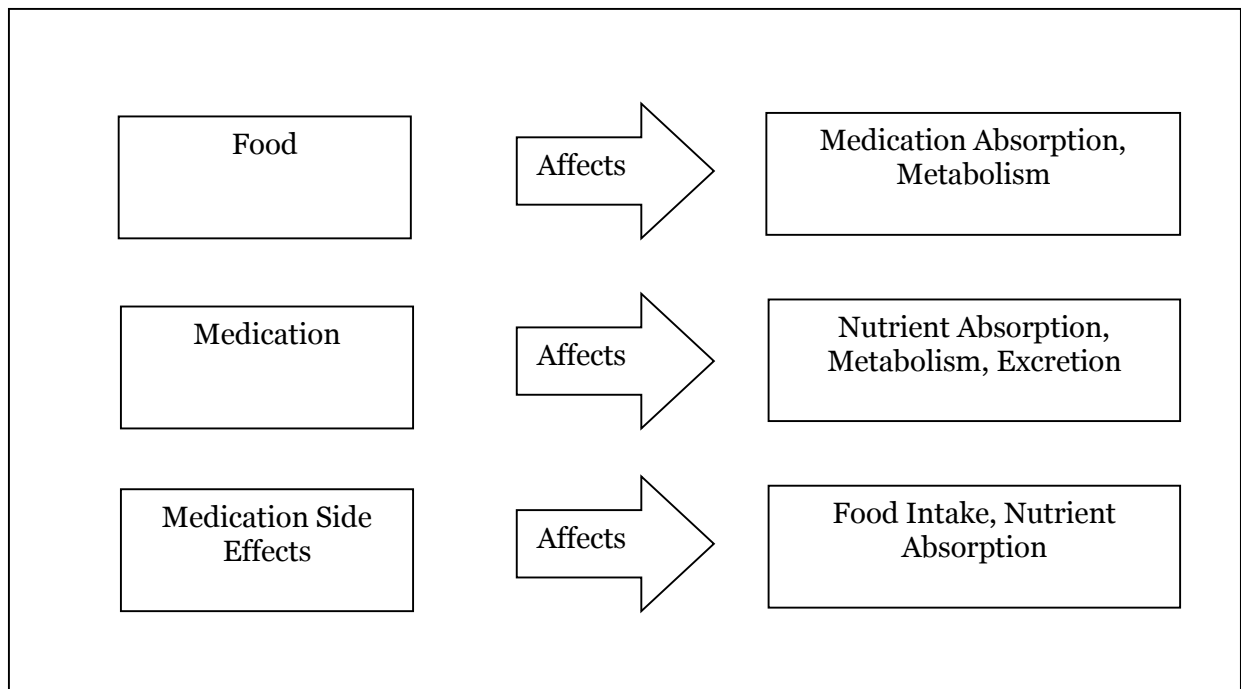


Figure 1. Types of food-ART medication interactions (Adapted from FANTA, 2004).



Figure 2. Map of Zambia (Source: Wikimedia Commons)

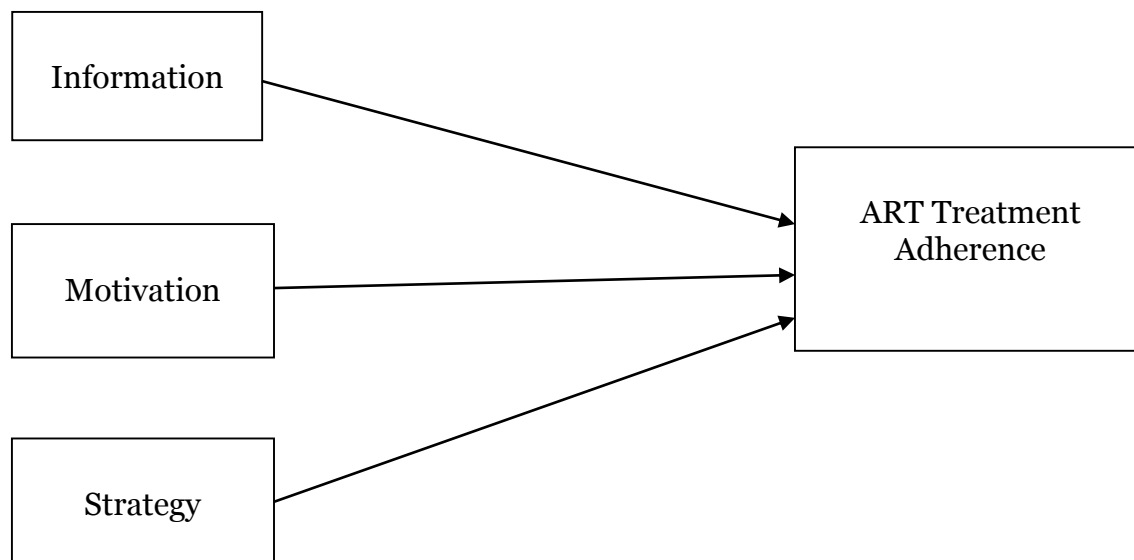


Figure 3. Information-Motivation-Strategy Model (Adapted from Martin et al., 2010)

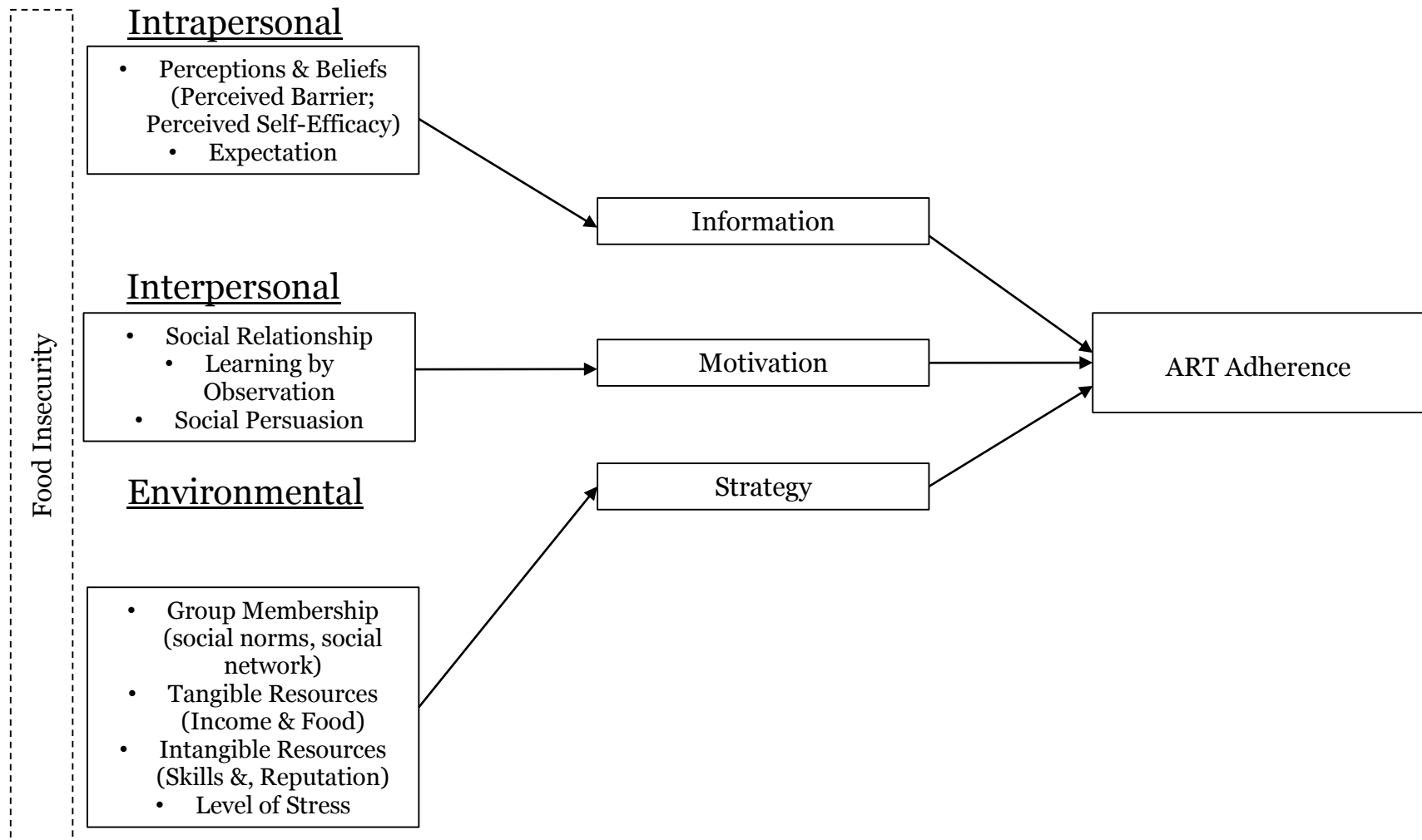


Figure 4. Integrated Conceptual Framework for Food Insecurity and ART Adherence

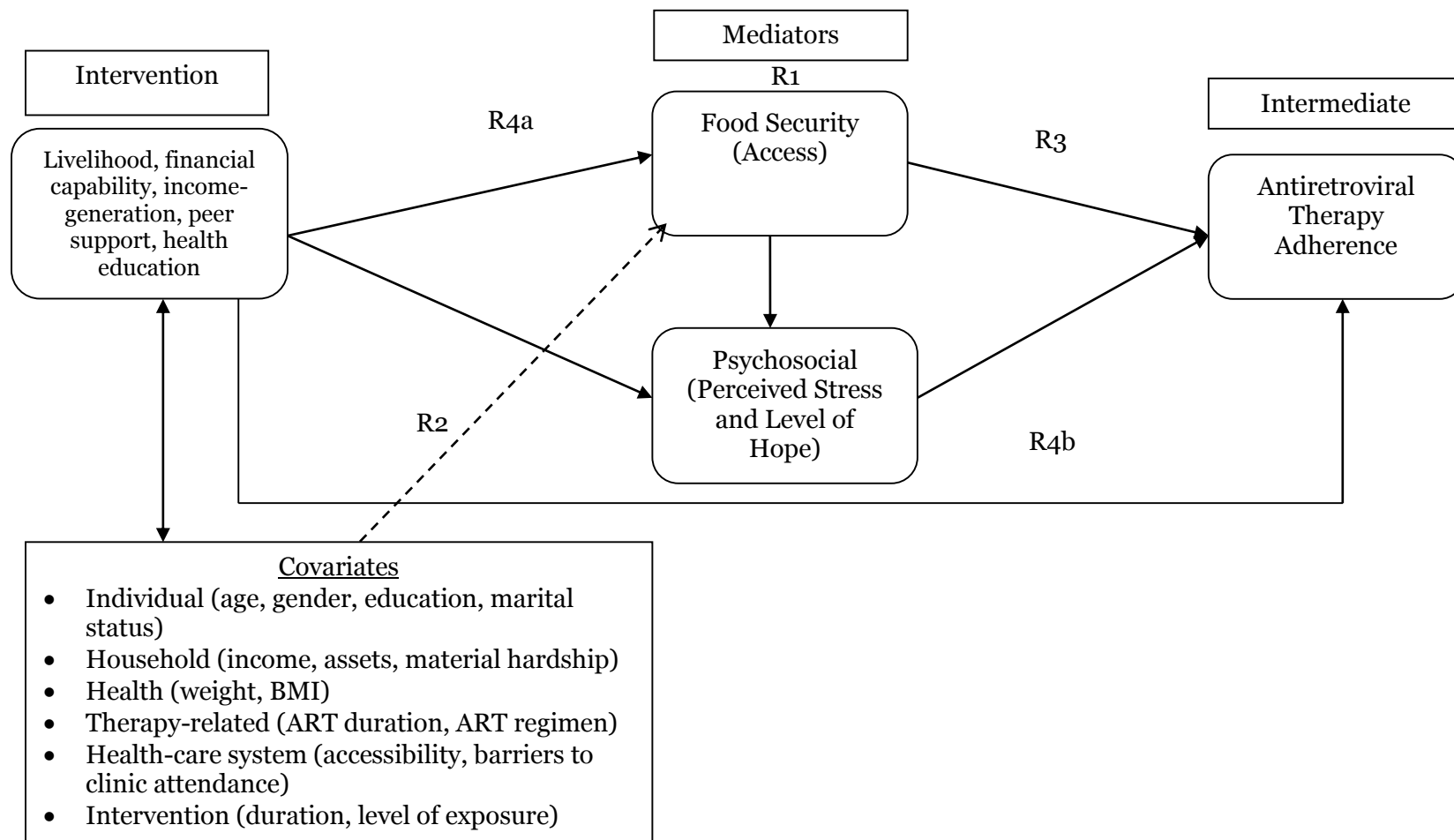


Figure 5. Integrated HIV and Livelihood Program Model

APPENDIX A: ANTIRETROVIRAL MEDICATIONS and RECOMMENDED FOOD INTAKES AND SIDE EFFECTS

Medication	Nutrition Recommendations	Food/Beverages to Avoid	Potential Side Effects
Nucleoside analog reverse-transcriptase inhibitors (NRTIs)			
Abacavir (ABC)	Can be taken without regard to food		Nausea, vomiting, fever, allergic reaction, anorexia, abdominal pain, diarrhea, anemia, rash, hypotension, pancreatitis, dyspnea, weakness and insomnia, cough, headache
Didanosine (ddl)	Take 30 minutes before or two hours after eating. Take with water only	Alcohol, juice	Anorexia, diarrhea, nausea, vomiting, pain, headache, weakness, insomnia, rash, dry mouth, loss of taste, constipation, stomatitis, anemia, fever, dizziness, pancreatitis
Lamivudine (3TC)	Can be taken without regard to food	Alcohol	Nausea, vomiting, headache, dizziness, diarrhea, abdominal pain, nasal symptoms, cough, fatigue, pancreatitis, anemia, insomnia, rash, and muscle pain
Stavudine (d4T)	Can be taken without regard to food	Limit alcohol	Nausea, vomiting, diarrhea, peripheral neuropathy, chills and fever, anorexia, stomatitis, anemia, headaches, rash and pancreatitis
Tenofovir (TDF)	With food, but do not take with a high fat meal	Alcohol	Abdominal pain, headache, fatigue, and dizziness
Zidovudine (AZT)	Can be taken without food, but if it causes nausea or stomach problems, take with a low fat meal. Do not take with a high fat meal	Alcohol	Anorexia, anemia, nausea, vomiting, bone marrow suppression, headache, fatigue, constipation, fever, dizziness, dyspnea, insomnia, muscle pain, rash
Non-nucleoside reverse-transcriptase inhibitors (NNRTIs)			
Efavirenz (EFV)	Can be taken with food, but do not take with a high fat meal	Alcohol	Elevated blood cholesterol levels, elevated triglycerides levels, rash, dizziness, anorexia, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence

Nevirapine (NVP)	Can be taken without regard to food	St. John's wort	Nausea, vomiting, rash, fever, headache, skin reactions, fatigues, stomatitis, abdominal pain, drowsiness, high hepatotoxicity
<hr/> Protease inhibitors (PIs)			
Indinavir (IDV)	Take on an empty stomach, one hour before or two hours after meal. Or take with a light non-fat meal. Drink at least 1,500 mL of fluid daily	St. John's wort	Nausea, abdominal pain, headache, kidney stones, taste changes, vomiting, diarrhea, insomnia, ascites, weakness, dizziness, may increase lipodystrophy
Lopinavir (LPV)	Can be taken without regard to food	St. John's wort	Abdominal pain, diarrhea, headaches, weakness, nausea, may increase the risk of lipodystrophy and or diabetes
Nelfinavir (NFV)	Take with meal or light snack.	St. John's wort	Diarrhea, flatulence, nausea, abdominal pain, rash, may increase the risk of lipodystrophy
Ritonavir (RTV)	Take with meal if possible	St. John's wort	Nausea, vomiting, diarrhea, hepatitis, jaundice, weakness, anorexia, abdominal pain, fever, diabetes, headache, dizziness, may increase the risk of lipodystrophy
Saquinavir (SQV)	Take with meal or light snack; take within two hours of a high fat meal and high calcium meal	Garlic supplement, St. John's wort	Mouth ulceration, taste changes, nausea, vomiting, abdominal pain, diarrhea, constipation, flatulence, weakness, rash, headache, may increase the risk of lipodystrophy

Adapted from FANTA (2004).

APPENDIX B: ANALYSIS OF INTERVENTIONS FOR FOOD SECURITY AND ART ADHERENCE

A. Program Design

Cost-effectiveness. Of the three interventions, FA programs may be the most cost-effective. Most FA programs for ART patients use food baskets that are supplied by international aid organizations, including UN's WFP and USAID. The use of locally produced and sourced foods can also decrease program costs. However, foods that require ingredients not locally available or produced (such as RUTF) may increase costs of FA programs. On the other hand, cost-effectiveness of IHLPs is unknown. Further, little is known whether CFALPs are more cost-effective than standalone interventions. Because combination programs include two distinct components, it may not be unreasonable to assume that CFALPs cost more to deliver and implement.

Extraneous factors. Each intervention is vulnerable to extraneous factors that may affect food supply or effectiveness of programs. Many FA programs depend on international aid community for cash and in-kind donations. Unless other sources of food aid are available, FA programs may run out of food baskets when support from aid organizations discontinue. Further, therapeutic feeding or nutrition supplementation programs may not always have adequate supply of RUTF particularly when production is done elsewhere because ingredients are not locally available. For livelihood programs, seasonal, meteorological (for example, drought), and infrastructure (for example, roads, transportations, and market demand and supply) constraints that are beyond the control of PLHIV may affect ability to produce food and earn income. When PLHIV are able to sell their products, HIV-positive market vendors may be discriminated because, for instance, of fear that buying food or produce from HIV-positive individuals will transmit HIV. Stigma and discrimination may pose additional barriers to PLHIV's ability to engage in and earn income from various livelihood activities. In addition,

when PLHIV get sick it may affect their ability to devote time and energy on their livelihood, which in turn, influence the capacity to generate income.

However, some interventions have established mechanisms that may facilitate and improve program effectiveness. For instance, CFALPs may provide an outlet for ART patients to market and sell their products. AMPATH, for example, purchases food for its FA program from local vendors, many of whom are AMPATH ART patients (Mamlin et al., 2009). This type of arrangement may encourage ART patients about the viability of their livelihood and addresses some market constraints that are beyond the patients' control.

Feasibility. Because of the target population's chronic health condition, which may deter PLHIV's ability to fully and actively participate in various programs, demonstrating that an intervention is feasible for this population is critical. All three interventions have been demonstrated to be feasible with ART patients in SSA. Of the three interventions, FA programs appear to be the most common and generally integrated with HIV treatment programs, followed by IHLPs and CFALPs (Aberman et al., 2014; Anema et al., 2012).

Household food security. Each intervention varies in its ability to address food security, including immediate and long-term access to food. Livelihood activities may have the best potential to sustainably provide PLHIV and their household access to adequate food by allowing them to produce their own food or earn income to purchase food, as opposed to solely relying on food assistance without dealing with the causes of food insecurity. IHLPs may also be better suited to intra-familial and inter-household sharing of food through increased food production and higher income to maintain adequate access to food for a longer period of time. Contrasted with IHLPs and CFALPs, FA programs are not designed to encourage income generation, household food production, and longer-term access to food. FA programs that only provide food to individual patients fail to address household food insecurity. Provision of food only to ART patients while other household members remain food insecure may lead to ethical concerns. Qualitative evidence suggests that food insecurity at the household level compels ART

patients who receive food aid to share food with other household members (Dibari et al., 2012; Ndirangu et al., 2014). As a result of food sharing, food aid may not last, for instance, the whole month as intended by the program and the ART patients may not get enough food needed for their health and treatment.

Incentives. Each intervention may have an incentivizing effect on clinic attendance, particularly regular collection of ARV drugs. For instance, some FA programs have combined the time when to collect food assistance with medication pick-up to encourage and motivate patients to collect medications as scheduled (Mamlin et al., 2009; Posse & Baltussen, 2013). IHLPs and CFALPs can also combine the timing of livelihood training sessions with clinic attendance to motivate patients to collect medications as scheduled and regularly attend clinical follow-ups to monitor CD4 count and other outcomes related to treatment efficacy. Combining the timing for food and medication pick-ups also saves patients' time, effort, and money.

Quantity and quality of food. Although access to food is important, access alone is not enough to ensure that ART patients are eating what is recommended for their health. The quantity and quality of food that PLHIV have access to is equally important. For instance, the quantity of food that ART patients receive through food assistance programs may not be enough when food is shared with other household members. Sharing of food is common among HIV-affected households in SSA, primarily because of food insecurity at the household level (Ndirangu et al., 2014). As a result of food sharing, ART patients may not eat enough food that benefits their health and treatment.

Actual food intake is also a concern when certain types of food provided by FA programs do not have similarities with the local diet. For instance, nutrition supplementation programs provide RUTF that may not have similarities with the local diet. Because of RUTF's incompatibility with the local diet, PLHIV may not regularly eat the supplement. RUTF may also have foreign and medicinal taste, which may also discourage ART patients from consuming the supplement. In some cases, ART patients have reported mixing RUTF with other food to lighten

the medicinal taste so that the supplement is more consistent with what patients are used to eat (Dibari et al., 2012). Obviously, not eating or mixing the supplement with other food reduces the food supplement's efficacy to improve nutrition and prevent weight loss among ART patients.

Quality of food is also an issue in regular food aid programs. In some cases, food basket items are not always compatible with the local diet. In other cases, program recipients may prefer to receive more diverse items in the food basket. For instance, patients prefer food basket that contains “softer” staples such as rice versus maize flour as the latter can be difficult to eat and swallow when patients are sick, and tastes poorly with ARVs (Ndirangu et al., 2014). Evidence suggests that quality and quantity of food remains a barrier to patient satisfaction with food assistance programs in SSA (Ndirangu et al., 2014; Posse & Baltussen, 2013). On the other hand, livelihood programs may allow PLHIV and their households to have more control and options with the quality and quantity of food that they buy and eat.

Replicability. Interventions for food security and health of PLHIV have varying degrees of replicability. Of the three interventions, FA programs are the most widely implemented and integrated with HIV treatment programs (Anema et al., 2012). FA programs may also be easier to replicate given their common program design. FA programs for ART patients build on FA programs for the general population and have taken advantage of existing programmatic models supported by international aid organizations. Contrasted with FA programs, IHLPs may be more operationally challenging to replicate. Limited financial and human (for example, training workers and facilities) resources have consistently emerged as critical barriers to replication and implementation of IHLPs (Datta & Njuguna, 2009; Kadiyala et al., 2009). For instance, many health workers are not trained on livelihood approaches so programs have to be delivered by separate training agents who have expertise in household economic security and income-generating activities (Aberman et al., 2014). On the other hand, health workers can be easily instructed to prepare and provide food baskets to ART patients.

Of the three interventions, CFALPs may be the most challenging to replicate. Because few HIV treatment programs are linked with CFALPs, little is known about the process and strategies to implement CFALPs. Most HIV treatment programs are only linked with one type of food security intervention (either food assistance or livelihood only). Organizations may experience additional challenges combining food assistance and livelihood components. Implementation barriers include financial and human resource-constraints, inadequate guidelines to determine who, when and how to transition FA participants to livelihood activities, and poor integration of food insecurity, health and economic data of ART patients (Kadiyala et al., 2009). For instance, many organizations have weak monitoring and evaluation systems that may not be capable of tracking key economic and health data that can be used by program staff to make decisions on which, when and how to transition ART patients from one program to the other and vice-versa (Yager, Kadiyala, & Weiser, 2011). However, combination programs may address some implementation issues that are common in standalone food security interventions. Horizontal integration of food security interventions can take advantage of existing resources to reduce operational costs which remain a significant barrier to replication of livelihood programs (Kadiyala et al., 2009). In Kenya, for instance, existing production farms are also used as demonstration farms to teach ART patients how to get the best yield out of their land (Mamlin et al., 2009). Because the organization (AMPATH) has the workforce capacity, AMPATH employees act as technical advisors that train ART patients. Use of existing organizational resources may reduce costs of hiring separate technical advisors and building physical training facilities, which most standalone livelihood programs need but cannot always afford.

Stability of access to food. Each intervention varies in its ability to provide a stable access to food. FA programs provide the least stable access to food, usually lasting only between six to 12 months. IHLPs may provide a more stable alternative to FA programs. Unlike standalone FA programs in which ART patients have to find other means to obtain food after 12

months or standalone livelihood programs in which ART patients have to find other means to obtain food while they are waiting to receive income or food from their income-generating activities, CFALPs may provide the most stable access to food in the immediate and long term. CFALPs have the benefits of direct provision of food to immediately rehabilitate nutrition, improve weight and regain energy, as well as an opportunity to create a more stable, sustainable and socially acceptable way of obtaining food through livelihood creation.

Suitability. Each intervention also has varying degrees of suitability or relevance to different groups of ART patients. Livelihood programs may not be appropriate for PLHIV who are severely malnourished, clinically unstable, or in the advanced stages of HIV infection because they may not have the physical capacity to carry out livelihood activities, including attending various training sessions. Similarly, labor-intensive activities may not be appropriate for PLHIV with limited strength and stamina. Instead, FA programs such as nutrition supplementation may be more suitable to undernourished PLHIV because immediate access to food can have exponential effects on nutrition rehabilitation and body composition. On the other hand, CFALPs may be suitable to different types of ART patients, regardless of physical strength and nutrition status. For instance, PLHIV who cannot begin livelihood activities because of limited strength and stamina can go first through food supplementation phase and regain energy and strength before transitioning to livelihood activities. The horizontal integration of programs provides a more holistic continuum of care that allows patients to rehabilitate and regain physical capacity before engaging in income-generating activities that require more energy and strength. CFALPs allow patients to recover sufficiently in the short term and create long-term strategies for food security.

Contrasted with FA programs, livelihood programs include a variety of activities that may not be relevant to all participants. For instance, Shamba Maisha would not be relevant to HIV-positive farmers with no land or with land but no access to adjacent supply of surface water for irrigation. Program planners need to be more innovative and engaged with community

stakeholders to identify feasible and viable income-generating activities locally. What works in urban areas may not work in rural areas. Similarly, agriculture or land-based livelihood may not always be the most viable option in rural areas. Uptake and effectiveness of livelihood activities may also be affected unless a loan or grant is offered to PLHIV to cover costs of starting an income-generating activity. For instance, a downpayment of US\$8 to receive a loan for purchase of a micro-irrigation pump might have excluded some PLHIV who could not afford the downpayment. Loans may also have negative impact on the ability of PLHIV to obtain food as any money they earn might be set aside to repay the loan than to buy food. A more interactive and participatory approach with local stakeholders leads to more appropriate and relevant solutions for food security within the context of HIV/AIDS (Swaans, Broerse, Meincke, Mudhara, & Bunders, 2009).

Sustainability of effects. Each intervention varies in its ability to sustain potential benefits to PLHIV's health. For some interventions, positive effects may only be evident during the duration of the program or immediately after the end of the program. For instance, FA programs have short duration with most programs lasting between six to 12 months. The short duration may not be able to sustain any positive effects on treatment adherence and other health outcomes such as weight and BMI. Evidence suggests that observed benefits from food assistance programs do not last after the end of the program (Ndekha, van Oosterhout, Salojee et al., 2009; van Oosterhout et al., 2010). This finding is not surprising given that any benefits occur primarily because of the food that participants receive. In other words, continuous food supplementation may be necessary, albeit not always feasible, to sustain positive benefits. Further, the short duration of FA programs may not have substantial and long-term impact on ART adherence because PLHIV need to adhere to treatment for the rest of their lives.

Although little is known about program duration of IHLs and CFALs, these interventions may be able to sustain any positive benefits to PLHIV over a longer period of time and more likely beyond the 6-12 months duration of FA programs. Compared with FA programs,

livelihood programs are geared towards creation of economic strategies that may provide a more stable access to food. For CFALPs, the effect of food supplementation on ART adherence and health of PLHIV may continue beyond the duration of the FA components because patients may be more motivated to take their medications as they learn and build opportunities to create a more stable and sustainable access to food.

Time lag of food benefits. FA programs (and the FA component of CFALPs) may result in quicker and more direct effects on nutrition and health because food for consumption is guaranteed to be received. FA programs may promptly alleviate nutritional deficits that accompany food insecurity and HIV, and may be particularly beneficial to undernourished ART patients. On the other hand, livelihood activities often require time to produce a benefit (e.g., food obtained from farms requires an entire season before harvest) and any benefits may not necessarily translate into food security and better nutrition. Unlike FA programs, IHLPs do not guarantee that food will be available and nutritious diet will be consumed by PLHIV.

B. Program Effectiveness

Evidence base. FA programs remain the most evaluated intervention and have the most empirical support. To date, few rigorous evaluations have been done to examine the impact of IHLPs and CFALPs on food security and health of ART patients. As stated earlier, a number of published intervention research have investigated the impact of FA on food security and various health outcomes of PLHIV, including treatment adherence, weight gain and body mass index, survival, immunologic, and quality of life (for example, Cantrell et al., 2008; Rawat et al., 2010, 2014; Tirivayi et al., 2012). Research and systematic reviews of the effects of food assistance – both nutritional supplementation and regular food aid – on adherence and other health outcomes of PLHIV are available (for example, Aberman et al., 2014; Ahoua et al., 2011; Audain et al., 2015; Drain et al., 2007; Mahlungulu, Grobler, Visser, & Volmink, 2007; Koethe, Chi, Megazzini, Heimburger, & Stringer, 2009). Compared with FA programs, the evidence base of IHLPs and CFALPs is limited and quality of causal evidence is weak. To date, only the effect

of FA programs on treatment adherence has been rigorously examined. Little is known about the effect of IHLPs and CFALPs on adherence behaviors of ART patients. However, qualitative and descriptive evidence suggests better adherence due to participation in livelihood programs (Ndirangu et al., 2014; Posse & Baltussen, 2013).

C. Potential Effects beyond Food Security and Better Health Outcomes

Livelihood activities may have effects beyond adequate access to food and better clinical outcomes. Evidence suggests that participation in livelihood programs have contributed to improved self-esteem and better standing in the community for PLHIV, as well as reduced stigma of HIV infection (Holmes et al., 2011; Holmes & Winskell, 2013; Yager et al., 2011; Wagner, Rana et al., 2012). A livelihood allows PHLIV and their families to earn income and obtain food in a more socially acceptable way. By giving opportunities to be economically productive and be able to provide for their families, PLHIV may experience higher self-esteem, greater self-efficacy and more optimistic view of the future. IHLPs may also empower PLHIV to be more engaged in local cultural, political and social activities. The ability to produce their own food and earn income, as opposed to solely relying on food assistance, may also reduce stigma of HIV infection by showing that PLHIV can be productive members of society. Livelihood programs may also incentivize PLHIV to adhere to treatment especially if PLHIV recognize that their ability to work depends on optimal adherence to ARV drugs. Economically-productive PLHIV on ART may also be role models to other people and may influence them to get tested and initiate treatment because they have witnessed positive benefits of ART. Contrasted with IHLPs and CFALPs, standalone FA programs do not explicitly address social aspects of food insecurity, including persistent anxiety about stability of food supply and the need to obtain food in a socially acceptable manner.

APPENDIX C: ARV DRUGS AND THE WHO TREATMENT GUIDELINES

ARV drugs are classified into six drug classes based on how the drugs treat or fight HIV; and the six drug classes comprise more than 25 ARV drugs. The drug classes include entry inhibitors (EI), fusion inhibitors (FI), reverse transcriptase inhibitors (RTI), integrase inhibitors (II), protease inhibitors (PI), and multi-class combination products. Reverse transcriptase inhibitors have two types - nucleoside reverse-transcriptase (NRTIs) and non-nucleoside reverse-transcriptase (NNRTIs). Available ARV drugs in the public sector in Zambia include the following: lamivudine (3TC), abacavir (ABC), zidovudine (AZT), stavudine (d4T), didanosine (ddI), efavirenz (EFV), emtricitabine (FTC), lopinavir/ritonavir (LPV/r), nevirapine (NVP), and tenofovir (TDF). 3TC, ABC, AZT, d4T, ddI, FTC, and TDF are NRTIs. Truvada, a brand-name combination of two NRTIs (tenofovir + emtricitabine), is also available. EFV and NVP are NNRTIs. LPV/r, a combination of two drugs (lopinavir + ritonavir), is a protease inhibitor and known by its brand name “Kaletra.” One multi-class combination product is also available. This ARV drug is more commonly known by its brand name “Atripla,” which combines EFV, FTC, and TDF.

Based on WHO recommendations (2013), first-line ART for adults should consist of two nucleoside reverse-transcriptase inhibitors (NRTIs) plus a non-nucleoside reverse-transcriptase inhibitor (NNRTI). A fixed-dose combination of TDF + 3TC (or FTC) + EFV is recommended as the preferred option to initiate ART. If TDF + 3TC (or FTC) + EFV is contraindicated or not available, WHO recommends one of the following alternative options: 1) AZT + 3TC + EFV; 2) AZT + 3TC + NVP; or 3) TDF + 3TC (or FTC) + NVP. Second-line ART for adults should consist of two NRTIs and a ritonavir-boosted protease inhibitor (PI). The WHO recommends a sequence of second-line NRTI options. After failure on a TDF + 3TC (or FTC)-based first-line regimen, AZT + 3TC is recommended as the NRTI backbone in second-line regimens. After failure on AZT + 3TC-based first-line regimen, TDF + 3TC (or FTC) is recommended as the NRTI backbone. Furthermore, use of NRTI backbones as a fixed-dose combination is the

preferred approach, whereas fixed-dosed combinations ATV/r and LPV/r are the preferred boosted PI options for second-line ART. In case patients do not respond well to second-line regimen, a third-line regimen can be prescribed. This regimen should include new drugs (e.g., integrase inhibitors and second-generation NNRTIs and PIs) with minimal risk of cross-resistance to previously used regimens. Currently, there are no third-line ART options available in the public sector in Zambia (MoH, 2010). In the absence of available and affordable third-line regimen, the WHO recommends that patients should continue with a tolerated regimen. In other words, every effort must be made to ensure that patients respond well to first- and second-line treatment regimens.

APPENDIX D: SELECTION OF LUNDAZI DISTRICT AND LUMEZI MISSION HOSPITALS

In order to determine which two health facilities were comparable and to be selected as project sites, all health facilities within Lundazi District were compared based on key indicators, including facility type, catchment population, size (e.g., number of beds per facility), access to free ART, standardized ART care (based on Ministry of Health guidelines), use of SmartCare,²⁵ accessibility, and availability of various health programs and services (for example, in-house pharmacy, nutrition counseling, food assistance, adherence counselors, lab and x-ray services).

As of 2012, Lundazi District had a total of 46 health facilities. Of the 46 facilities, 24 were health centers (23 rural, 1 urban), 21 health posts, and one level-1 or district hospital (MoH, 2013). All 21 health posts were eliminated from the selection process because HIV treatment and related services are not available at these facilities. Fourteen health centers with a catchment population of less than 10,000 were also excluded because smaller catchment sizes might not be sufficient to recruit and enroll at least 50 ART patients who meet the inclusion criteria. After excluding all health posts and health centers with small catchment population, the number of eligible health facilities was reduced to 11. Of the 11 facilities, only three – Lumezi Mission Hospital (LMH), Lundazi District Hospital (LDH), and Kanyanga Rural Health Center (KRHC) – have at least 20 beds. The other eight facilities have between one to 19 beds. The three remaining health facilities provide free and standardized ART; run SmartCare to record patient data; and offer nutrition counseling, food assistance (usually therapeutic feeding), HIV-related services (e.g., HIV counseling and testing, prevention of mother-to-child transmission) and other medical services such as emergency obstetric care, pharmacy, lab services and dental services. Unlike LMH and LDH, KRHC does not have on-site adherence counselors. Given that medication adherence counseling was the treatment-as-usual component of the project, a health

²⁵ SmartCare is an electronic health record system that stores a person's data. SmartCare was developed to improve continuity of health care and provide timely data on HIV/AIDS (and other health) programs and services.

facility with available adherence counseling was required. Finally, LDH and LMH are operating as de jure and de facto level 1 hospitals, respectively. As a result, only LDH and LMH have on-site physicians (V. Nyirenda, personal communication, August 4, 2014). Other health facilities in Lundazi District are staffed by nurses. Considering all these variables, LDH and LMH were the two most comparable health facilities; and thus, were selected for the project. ART patients in LDH and LMH do not overlap. In other words, patients registered at LDH do not go to LMH for their ART visits, or vice-versa. Table 14 illustrates the comparability between LDH and LMH.

Lundazi District Hospital. LDH, so far, is the only MOH-approved level 1 or district hospital in Lundazi District. LDH is government-owned and serves the entire population of Lundazi District. Being a level 1 hospital, LDH provides general medical, surgical, obstetric and diagnostic services. LDH has at least 2,500 active adult ART patients; and sees about 50 ART clients per day. In addition to active ART patients, LDH has nearly 3,000 PLHIV on pre-ART, i.e., based on the revised WHO guidelines, these patients are not yet in need of ART. Overall, LDH has more than 5,500 patients who are living with HIV (D. Kamanga, personal communication, August 5, 2014; V. Nyirenda, personal communication, June 19, 2015). LDH is located on the main street of Lundazi and less than a kilometer from the District Health and Medical Office.

Lumezi Mission Hospital. LMH is currently operating as a level 1 hospital, although it is classified as a rural health center. The process of upgrading LMH to a level 1 referral hospital is pending approval from the Ministry of Health (V. Nyirenda, personal communication, August 5, 2014). LMH also provides general medical, surgical, obstetric and diagnostic services. LMH is a faith-based facility being run mainly by the Catholic Sisters of Kilimanjaro. LMH has a catchment population of 35,390 and 16 outreach sites located in the southwestern area of Lundazi District (MoH, 2013). LMH has at least 600 active adult ART patients; and sees about 30 ART clients per day. In addition to active ART patients, LMH has more than 300 PLHIV on pre-ART. Overall, LMH has more than 1,000 patients who are living

with HIV (D. Kamanga, personal communication, August 5, 2014; V. Nyirenda, personal communication, June 19, 2015). LMH is located on the road connecting Lundazi to Chipata and is 35 kilometers away from the District Health and Medical Office.

Table 14

Comparison of Lundazi District and Lumezi Mission Hospitals

Indicators	Lundazi District Hospital	Lumezi Mission Hospital
Facility type	Level 1 Hospital	Level 1 Hospital
Facility owner	Government	Mission
Catchment population	314,281	35,390
Number of outreach sites	n/a	16
Distance from health facility to farthest outreach site (in kilometers)	n/a	60
Distance of facility to District Health and Medical Office (in kilometers)	< 1	35
Number of HIV+ patients	> 5,500	> 1,000
Adult patients on ART	≥ 2,500	≥ 600
Adult patients on pre-ART	3,000	> 300
Number of beds per facility	110	140
Access to free ART	✓	✓
Standardized ART care	✓	✓
On-site physicians	✓	✓
Use of SmartCare	✓	✓
Health service availability		
In-house pharmacy	✓	✓
Nutrition counseling	✓	✓
Therapeutic feeding	✓	✓
Adherence counseling (on-site)	✓	✓
Lab services	✓	✓
X-ray services	✓	✓
HIV counseling and testing	✓	✓
Prevention of mother-to-child transmission	✓	✓
Emergency obstetric care	✓	✓
Pharmacy lab services	✓	✓
Dental services	✓	✓
CD4 machine	✓	x

APPENDIX E: COVARIATE SELECTION

Table 15

Covariate selection using logistic regression analysis of baseline ART adherence (visual analog scale) and ART patient characteristics with estimates on coefficient and respective standard error using complete-case analysis

Variables	ART Adherence (Visual Analog Scale)			
	Model 1 OR (Robust SE)	Model 2 OR (Robust SE)	Model 3 OR (Robust SE)	Model 4 OR (Robust SE)
Demographic				
Age (in years)	1.00 (0.04)	0.99 (0.05)	0.92 (0.05)	
Gender (reference is female)	1.22 (0.81)	1.05 (0.83)	0.80 (0.62)	
Marital status (reference is not married)	0.45 (0.31)	0.39 (0.36)	0.59 (0.69)	
Education level (reference is primary education)	0.66 (0.36)	0.28 (0.24)	0.23 (0.25)	
Type of occupation (reference is farming)	0.59 (0.47)	0.18 (0.19) [†]	0.07 (0.09)*	0.17 (0.15)*
Head of household status (reference is non-head of household)	0.78 (0.63)	0.68 (0.62)	0.33 (0.40)	
Residence (reference is Lundazi)	0.57 (0.35)	0.36 (0.37)	0.04 (0.06)*	0.15 (0.13)*
Social and Economic				
Household size		1.11 (0.14)	1.01 (0.17)	
Financial situation (reference is worse than two years ago)		4.13 (4.11)	5.59 (7.44)	
Household income (reference is K0 – K20)				
K21 – K50		0.54 (0.43)	0.42 (0.41)	
K51 – K500		0.89 (0.88)	0.48 (0.72)	
≥K501		2.74 (5.03)	1.39 (3.89)	
Transportation asset index		0.02 (0.03)**	0.00 (0.01)**	0.06 (0.06)**
Household possessions index		0.89 (0.56)	1.15 (0.90)	
Livestock ownership index		1.09 (0.18)	1.32 (0.28)	1.21 (0.12)*
Landownership (in acreage)		1.10 (0.12)	1.14 (0.21)	
Saving behavior (reference is do not save)		2.07 (1.58)	12.22	

Debt (reference is no debt)		0.55 (0.41)	(15.85) [†] 0.45 (0.50)	
Health				
Perceived stress, distress			1.01 (0.12)	
Perceived stress, coping			1.16 (0.22)	
Health perception ¹			6.36 (4.15)**	2.36 (0.78)*
ART treatment duration (in months)			1.00 (0.03)	
Barriers to pill taking			0.95 (0.04)	
Pill burden (reference is more than one pill)				
			0.21 (0.28)	
Body mass index			0.77 (0.13)	
Distance to health facility			1.06 (0.04)	
Time to travel to health facility			1.00 (0.01)	
Hosmer-Lemeshow test	$\chi^2(62) = 68.13$ $p = 0.2765$	$\chi^2(60) = 77.67$ $p = 0.0622$	$\chi^2(51) = 74.97$ $p = 0.0161$	$\chi^2(42) = 41.52$ $p = 0.4920$
<i>N</i>	79	79	79	79

¹ For this analysis, health perception was treated as an interval variable. I performed a series of likelihood ratio (LR) tests that compared a model with only the ordinal health perception variable to a model that included both the ordinal variable and all but two of the dummy health perception variables, in addition to all other covariates. For each LR test, the results were not significant ($p > .05$) which indicated that the dummy variables did not add more information to the model. In other words, treating an ordinal variable (health perception) as an interval variable did not lead to a loss of information about the association between health perception and optimal treatment adherence (Long & Freese, 2006).

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test. Note: robust SE = robust standard error.

Table 16

Covariate selection using logistic regression analysis of baseline ART adherence (medication possession ratio), food insecurity and ART patient characteristics with estimates on coefficient and respective standard error using complete-case analysis

Variables	ART Adherence (Medication Possession Ratio)			
	Model 1 OR (Robust SE)	Model 2 OR (Robust SE)	Model 3 OR (Robust SE)	Model 4 OR (Robust SE)
Demographic				
Age (in years)	1.03 (0.04)	1.05 (0.04)	0.97 (0.06)	
Gender (reference is female)	1.75 (1.13)	1.87 (1.45)	1.66 (1.62)	
Marital status (reference is not married)	0.76 (0.44)	0.63 (0.42)	0.22 (0.21)	
Education level (reference is primary education)	0.46 (0.23)	0.36 (0.23) [†]	0.12 (0.11)*	0.22 (0.17) [†]
Type of occupation (reference is farming)	0.97 (0.72)	0.55 (0.52)	0.59 (0.86)	
Head of household status (reference is non-head of household)	0.35 (0.24)	0.34 (0.27)	0.18 (0.23)	
Residence (reference is Lundazi)	0.34 (0.21) [†]	0.21 (0.19) [†]	2.00 (2.76)	
Social and Economic				
Household size		1.00 (0.09)	0.95 (0.10)	
Financial situation (reference is worse than two years ago)		0.42 (0.32)	0.01 (0.02)**	0.05 (0.05)**
Household income ²		1.71 (0.40)*	5.61 (2.95)**	3.46 (1.18)***
Transportation asset index		0.12 (0.14) [†]	0.02 (0.03)*	0.06 (0.06)**
Household possessions index		0.63 (0.30)	3.15 (2.95)	
Livestock ownership index		1.07 (0.17)	1.18 (0.22)	
Landownership (in acreage)		0.92 (0.07)	0.87 (0.08)	
Saving behavior (reference is do not save)		0.75 (0.56)	8.13 (10.37) [†]	
Debt (reference is no debt)		0.35 (0.22) [†]	0.08 (0.07)**	0.21 (0.17) [†]
Health				
Perceived stress, distress			1.23 (0.16) [†]	1.11 (0.10)
Perceived stress, coping			1.72 (0.28)**	1.26 (0.13)*
Health perception (reference is poor/fair)			2.00 (1.97)	
ART treatment duration (in months)			0.96 (0.02) [†]	0.98 (0.01) [†]

Barriers to clinic attendance				0.92 (0.05) [†]
Pill burden (reference is more than one pill)				1.76 (1.46)
Body mass index				0.80 (0.11) [†]
Distance to health facility				0.87 (0.04)**
Time to travel to health facility				1.02 (0.01)***
				0.88 (0.03)**
				1.02 (0.00)***
Hosmer-Lemeshow test	$\chi^2(71) = 78.33$	$\chi^2(72) = 85.36$	$\chi^2(63) = 57.94$	$\chi^2(78) = 71.36$
	$p = 0.2578$	$p = 0.1345$	$p = 0.6568$	$p = 0.6891$
<i>N</i>	89	89	89	89

¹ For this medication possession ratio, optimal adherence was set at the $\geq 95\%$ level.

² For this analysis, household income was treated as an interval variable. I performed a series of likelihood ratio (LR) tests that compared a model with only the ordinal income variable to a model that included both the ordinal variable and all but two of the dummy income variables, in addition to all other covariates (Long & Freese, 2006). For each LR test, the results were not significant ($p > .05$) which indicated that the dummy variables did not add more information to the model. In other words, treating an ordinal variable (household income) as an interval variable did not lead to a loss of information about the association between household income and medication possession ratio.

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test. Note: robust SE = robust standard error.

Table 17

Covariate selection using logistic regression analysis of baseline ART adherence (visual analog scale), food insecurity and ART patient characteristics with estimates on coefficient and respective standard error using multiply imputed data (m = 20)

Variables	ART Adherence (Visual Analog Scale)			
	Model 1 OR (Robust SE)	Model 2 OR (Robust SE)	Model 3 OR (Robust SE)	Model 4 OR (Robust SE)
Demographic				
Age (in years)	0.99 (0.04)	0.99 (0.05)	0.97 (0.05)	
Gender (reference is female)	0.82 (0.51)	0.87 (0.61)	1.08 (1.01)	
Marital status (reference is not married)	0.66 (0.42)	0.74 (0.54)	0.70 (0.64)	
Education level (reference is primary education)	0.79 (0.41)	0.58 (0.44)	0.48 (0.38)	
Type of occupation (reference is farming)	0.78 (0.58)	0.46 (0.44)	0.15 (0.16) [†]	0.32 (0.25)
Head of household status (reference is non-head of household)	1.03 (0.71)	0.87 (0.68)	0.41 (0.48)	
Residence (reference is Lundazi)	0.56 (0.33)	0.58 (0.57)	0.11 (0.16)	0.20 (0.15) [*]
Social and Economic				
Household size		0.96 (0.11)	0.89 (0.11)	
Financial situation (reference is worse than two years ago)		1.72 (1.51)	3.32 (3.84)	
Household income (reference is K0 – K20)				
K21 – K50		0.59 (0.43)	0.44 (0.40)	
K51 – K500		0.61 (0.63)	0.36 (0.56)	
≥K501		1.50 (2.27)	0.59 (1.25)	
Transportation asset index		0.10 (0.10) [*]	0.02 (0.02) [*]	0.11(0.09) ^{**}
Household possessions index		1.05 (0.62)	1.45 (1.16)	
Livestock ownership index		1.18 (0.20)	1.39 (0.30)	1.20 (0.13) [†]
Landownership (in acreage)		1.07 (0.09)	1.13 (0.17)	
Saving behavior (reference is do not save)		2.35 (1.83)	12.38 (17.57) [†]	
Debt (reference is no debt)		0.64 (0.44)	0.57 (0.56)	

Health				
Perceived stress, distress	0.99 (0.11)			
Perceived stress, coping	1.17 (0.21)			
Health perception ¹	3.89 (2.03)*		2.05 (0.63)*	
ART treatment duration (in months)	0.98 (0.02)			
Barriers to pill taking	0.94 (0.04)			
Pill burden (reference is more than one pill)				
	0.70 (0.72)			
Body mass index	0.90 (0.14)			
Distance to health facility	1.04 (0.03)			
Time to travel to health facility	1.00 (0.00)			
<i>N</i>	101	101	101	101

¹ For this analysis, health perception was treated as an interval variable. I performed a series of likelihood ratio (LR) tests that compared a model with only the ordinal health perception variable to a model that included both the ordinal variable and all but two of the dummy health perception variables, in addition to all other covariates. For each LR test, the results were not significant ($p > .05$) which indicated that the dummy variables did not add more information to the model. In other words, treating an ordinal variable (health perception) as an interval variable did not lead to a loss of information about the association between health perception and optimal treatment adherence (Long & Freese, 2006).

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test. Note: robust SE = robust standard error.

Table 18

Covariate selection using logistic regression analysis of baseline ART adherence (medication possession ratio), food insecurity and ART patient characteristics with estimates on coefficient and respective standard error using multiply imputed data (m = 20)

Variables	ART Adherence (Medication Possession Ratio)			
	Model 1 OR (Robust SE)	Model 2 OR (Robust SE)	Model 3 OR (Robust SE)	Model 4 OR (Robust SE)
Demographic				
Age (in years)	1.03 (0.04)	1.04 (0.04)	1.01 (0.04)	
Gender (reference is female)	1.77 (1.15)	1.84 (1.32)	1.64 (1.24)	
Marital status (reference is not married)	0.77 (0.43)	0.72 (0.44)	0.42 (0.28)	
Education level (reference is primary education)	0.44 (0.22)	0.42 (0.23)	0.30 (0.21) [†]	0.45 (0.27)
Type of occupation (reference is farming)	1.50 (0.97)	1.20 (1.10)	1.71 (1.99)	
Head of household status (reference is non-head of household)	0.35 (0.23)	0.38 (0.27)	0.29 (0.25)	
Residence (reference is Lundazi)	0.40 (0.21) [†]	0.24 (0.19) [†]	0.79 (0.98)	
Social and Economic				
Household size		1.00 (0.09)	0.93 (0.10)	
Financial situation (reference is worse than two years ago)		0.72 (0.56)	0.28 (0.29)	0.33 (0.41)
Household income ²		1.20 (0.28)	1.55 (0.54)	1.70 (0.62)
Transportation asset index		0.35 (0.36)	0.51 (0.63) [*]	0.40 (0.33)
Household possessions index		0.79 (0.37)	2.48 (1.72)	
Livestock ownership index		1.03 (0.14)	0.99 (0.19)	
Landownership (in acreage)		0.95 (0.06)	1.03 (0.11)	
Saving behavior (reference is do not save)		0.88 (0.54)	3.19 (3.22)	
Debt (reference is no debt)		0.33 (0.19) [†]	0.17 (0.12) [*]	0.26 (0.17) [*]
Health				
Perceived stress, distress			1.51 (0.11)	1.08 (0.07)
Perceived stress, coping			1.37 (0.18) [*]	1.10 (0.10)

Health perception (reference is poor/fair)	1.07 (0.41)	
ART treatment duration (in months)	0.97 (0.02)	0.98 (0.01)
Barriers to clinic attendance	0.92 (0.04) [†]	
Pill burden (reference is more than one pill)	1.50 (1.00)	
Body mass index	0.85 (0.2)	
Distance to health facility	0.95 (0.05)	0.92 (0.04) [†]
Time to travel to health facility	1.01 (0.00)*	1.01 (0.00)*
<i>N</i>	101	101

¹ For this medication possession ratio, optimal adherence was set at the $\geq 95\%$ level.

² For this analysis, household income was treated as an interval variable. I performed a series of likelihood ratio (LR) tests that compared a model with only the ordinal income variable to a model that included both the ordinal variable and all but two of the dummy income variables, in addition to all other covariates (Long & Freese, 2006). For each LR test, the results were not significant ($p > .05$) which indicated that the dummy variables did not add more information to the model. In other words, treating an ordinal variable (household income) as an interval variable did not lead to a loss of information about the association between household income and medication possession ratio.

[†] $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$, two-tailed test. Note: robust SE = robust standard error

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