A PROSPECTIVE STUDY TO ASSESS THE FACTORS AFFECTING NUTRITIONAL STATUS OF PEOPLE LIVING WITH HIV/AIDS (PLHA) RECEIVING

ANTI-RETROVIRAL THERAPY (ART)

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DECLARATION BY THE CANDIDATE

I hereby declare that this thesis entitled *"A PROSPECTIVE STUDY TO ASSESS THE FACTORS AFFECTING NUTRITIONAL STATUS OF PEOPLE LIVING WITH HIV/AIDS (PLHA) RECEIVING ANTI-RETROVIRAL THERAPY (ART)"* is a bonafide and genuine research work carried out by me under the guidance of **DR SHAILAJA S PATIL**, HOD & Professor, Department of Community Medicine, BLDE (Deemed to be University), Shri B M Patil Medical College, Hospital & Research Centre, Vijayapura, Karnataka India. No part of this thesis has been formed the bases for the award of any degree or fellowship previously.

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Place   **Dr Ravishekar N Hiremath**

Date

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Abbreviations	
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
PLHA	People living with HIV/AIDS
NACP	National AIDS Control Programme
NACO	National AIDS Control Program
ART	Antiretroviral treatment
HAART	Highly Active Antiretroviral Therapy
BMI	Body-mass-index
WHO	World Health Organisation
WaSH	Water Sanitation and Hygiene
IEC	Information, Education and Communication
MSACS	Maharashtra State AIDS control society
ISAQ	International Standards of Anthropometric Assessments
QOL	Quality of Life
HFIAS	Household Food Insecurity Access Scale

BMI	Body Mass Index
VAS	visual analogue scale
APL	Above Poverty Line
BPL	Below Poverty Line
OIs	Opportunistic infections
HB	Hemoglobin
Alb	Albumin
USAID	United States Agency for International Development
BCC	Behaviour change communication

ABSTRACT

Background: The current HIV/AIDS (Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome) pandemic is a worldwide concern, the impact of which is expected to be felt over the years ahead, with critical public health implications. Focus on improving nutrition in HIV/AIDS patients is vital and the need of the hour. This is because, proper nutrition not only optimizes existing immune system function, but can significantly reduce the incidence of HIV-related complications and improves the patient's quality of life. Nutritional management among PLHA is hence an essential but often neglected element in the HIV continuum of care and efforts need to be invested in studying as well as understanding the complicated web of associated factors. The main aim of the study was to assess the nutritional status and socio-demographic factors of ART-Naïve PLHA and their association, by prospectively following them for one year.

Materials and Methods: A Prospective study was carried out among ART-naive PLHA, registered in five Institutional ART centers in Pune, Maharashtra and followed up for one year from their inclusion date in the study. Accounting for 15% loss-to-follow-up, the sample size was estimated to be 430. Systematic random sampling was employed to achieve the target sample size from all five ART centers. Ethical clearance was obtained from the Institutional Ethical Clearance Committee. All patients were recruited for the study on a voluntary basis, confidentiality was ensured in every step. Data was collected by means of personal interview and anthropometric measurements and relevant blood investigations were carried out as per study protocol.

Results: Overall, 430 participants were enrolled in the study, and baseline data were collected from them. However, only 378 remained till the end of the study period (13 months) and were included in the final analysis. With the mean age of the study cohort of 41yrs, and even after one year of treatment, undernutrition in our study was at 34.9%, anaemia at 59.9%, low albumin at

12.9%, low total protein at 13.8%, which were higher in spite of regular treatment and monitoring. 72% were consuming an inadequate diet. The majority, 57.1%, had a poor Quality of life (QoL) index, while 31.5% and 11.5% had good and excellent QoL indices, respectively and the majority, 52.9% showed food insecurity. Chi-square test of independence was used to test the association which showed, No or same Job, decreased or no income, food insecurity, poor quality of life, decreased level of haemoglobin, low before-after perceived health status, after 1 year of ART were significant predictors of low nutrition status. Also, female respondents were significantly at higher risk of low nutrition status while on ART. The study also showed the majority of the PLHA practiced wrong cooking/poor eating habits and consumed unpasteurized milk. Few of the Water, sanitation and hygiene (WaSH) and food consumption patterns showed alarming practices which needed to be changed. These practices are the "Art of preserving life" in this century where in communicable diseases are at high, especially in developing nations. About 31% of the subjects were found to be overweight/obese, with 32% being tobacco users and 8.31% alcohol drinkers, flagging the need to implement preventive measures for Non communicable diseases (NCDs) even among PLHAs.

Conclusion: Poor/no income, job insecurity, food insecurity, poor QoL, anaemia at the end of one year of ART, female gender and those living in urban areas were significant predictors of undernutrition among PLHA. Synergistic effects of malnutrition, food insecurity, poor diet and health status influence poor outcomes in the already compromised household conditions due to increased financial constraints with superimposed emotional breakdown. Hence, even a tiny fraction in weight loss would result in significant morbidity and decreased survival rate among PLHA. Study findings also recommended PLHA to follow good WaSH practices and cooking/eating habits, as these factors act synergistically with other factors to affect the holistic

health of PLHA. The study findings also indicate the incorporation of early screening for NCD risk factors among PLHA, to prevent and manage the same at the earliest, before it can aggravate the already compromised immune status among PLHA.

Key words: HIV/AIDS, Nutrition, Food insecurity, Quality of life, Obesity, Hygiene

INTRODUCTION

From Despair & Death…., To longevity and Life

"The HIV epidemic not only affects the health and life of individuals, but it also impacts households, communities and the development and economic growth of entire nations".

The current HIV/AIDS (Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome) pandemic is a worldwide concern, the impact of which is expected to be felt over the years ahead, with critical public health implications. Albeit India has a low prevalence of HIV infection of 0.22%, given the background of the high number of people under the high-risk group, HIV still pulls itself as an epidemic in the country with a heterogeneous spread across the vast boundaries of the country inflicting the vulnerable population predominantly[1]. Though HIV prevalence in the adult population (15-49 years) has declined from the estimated level of 0.41% in 2001 to 0.22% in 2019, India continues to have the highest number of PLHA (People living with HIV/AIDS), positioning itself third (3rd) in rank with South Africa being the first[2]. These PLHA face serious health issues predominantly in the form of opportunistic infections (some occurring concomitantly). They also face financial constraints; as well as social problems, including stigma within the family and in the surrounding society. To combat the morbidity and mortality associated with Human Immuno-deficiency Virus/ Acquired immune deficiency syndrome (HIV/AIDS) in India., the National AIDS Control Programme (NACP) was launched in 1992 in a phased manner. Based on the lessons learnt, the Government of India (GoI) designed a strategy for the fourth phase of NACP (NACP-IV: 2012-17). NACP-IV aims to accelerate the reversal of the HIV/AIDS epidemic in the country by means of integrating NACP with the other National health programmes.

The main objectives of NACP-IV are to Halve the incidence of new infections annually and to provide comprehensive care and support to PLHA's along with standard treatment[3].

The National AIDS Control (NACO) Program initiated the free antiretroviral treatment (ART) program in 2004 for all HIV patients with a CD4 count of less than 350 cells /mm3. As per NACO annual report 2012-13, 17.36 lakh PLHA have registered at 380 ART centres across the country, of whom 6.04 lakh clinically eligible patients (including 34,367 children) are receiving free ART at government health facilities[3].

As a result of use of Highly Active Antiretroviral Therapy (HAART) since 1996, the course of HIV infection and quality of life of PLHA has changed significantly. HAART suppresses viral replication and thereby the viral load, allowing the recovery of the individual's immune system. Hence, AIDS-associated mortality and morbidity have declined to a large extent after the widespread introduction of HAART[4]. However, the mere introduction of HAART will not help in the improvement of the quality of the life of the individuals. So comprehensive and holistic approach is needed to support them to lead a good quality of life. One of the essential concerns that surround PLHA is access to good food and nutrition security. Weight loss and malnutrition remain common problems for those diagnosed late in the course of the infection and those with failed or non-adherent ART regimens[5]. Studies from India have shown dietary intake concerning nutritional adequacy and quality has been poor, highlighting the poor access to nutritious foods among the impoverished[6,7]. Hence, mere focus on HAART without considering the nutritional needs of individuals with HIV/AIDS can in fact underplay the effects of HAART as nutrition and the immune system are interconnected.

Antiretroviral treatment (ART) not only reconstitutes the individual's immune function, reflected in a clinical improvement, but also influences a significant weight gain, provided the diet contains adequate energy, protein and micronutrients in the proper proportions. Reduced body-mass-index (BMI) is predictive of mortality with ART and highlights the role and value of monitoring BMI for nutritional monitoring and support, in addition to adherence to antiretroviral medications. Reduced food intake, both in terms of quality and quantity, can adversely bring down the efficacy of ART regimens. This happens, as some drugs may be poorly absorbed or can cause significant side effects if not taken with adequate food. Studies among HIV-infected adults from African countries have showed that with good ART adherence and micronutrient supplementation, there was significant increase in weight gain and CD4 counts[8-11]. Although ART is available and accessible to even the most difficult to reach areas in India, nutritional needs and further care have been ignored and not studied among PLHA's even though malnutrition is a commonly associated with the disease[12].

Impaired nutritional status reflects reduced food consumption in terms of quantity as well as quality. The body of an individual with HIV infection requires additional nutrition in addition to the regular intake. Studies across the world have demonstrated that AIDS-afflicted households incur an escalated health-care expenditure, and this accounted for almost a whopping 80% of the household health-care budget. Thus, chances of family being pushed to below the poverty line goes high[13]. Further, malnutrition not only worsens the HIV status and hastens progression to AIDS-related illnesses, but also increases the chances of transmission to others, as seen in parental-to-child transmission[13].

Along with food insecurity, malnutrition may hinder the individual affecting treatment adherence and thereby, response to ART, exacerbating the vicious cycle of poverty and infection. HIV status

compromises the nutritional status of an individual by reducing optimum work capacity and productivity, jeopardizing household income[14]. World Health Organisation recommends improved attention to diet and nutrition, which will enhance ART acceptability, adherence and effectiveness. It has also directed countries to prepare for ART access through training in the nutritional dimension of HIV/AIDS[15].

During the planning phase of NACP IV, the necessity of expanding PLHA socio-economic rehabilitation packages including nutrition aspects was envisaged by all. It was agreed that the plan should be differentiated to clearly show the contribution by other Ministries towards this end, as part of a multi-sectoral approach to tackle HIV/AIDS[16].

Focus on improving nutrition in HIV/AIDS patients is vital and the need of the hour. This is because, proper nutrition not only optimizes existing immune system function, but can significantly reduce the incidence of HIV-related complications and improves the patient's quality of life[6]. Nutritional management among PLHA is hence an essential but often neglected element in the HIV continuum of care and efforts need to be invested in studying as well as understanding the complicated web of associated factors. Keeping in view the socio-economic constraints faced by PLHA, particularly in resource-limited settings like India and much needed appropriate strategies for improving nutritional status, there is a need to carry out this study for strengthening the continuum of care for PLHA.

REVIEW OF LITERATURE

2.1 *Global HIV Scenario*

It was in 1981, five cases of *Pneumocystis carnii* pneumonia (PCP) among homosexuals who were previously healthy young men, were reported in the USA who later died. On further investigation, "cellular immune dysfunction related to common exposure" was suggested and was labelled as "disease acquired through sexual contact" which was later on discovered as due to HIV (Human Immunodeficiency virus) leading to AIDS (Acquired Immunodeficiency syndrome) [17].

As per UNAIDS, globally, 38.0 million people are living with HIV (2019) and 1.7 million people have newly been infected with HIV (2019) and around 6.9 lakh people died of AIDS-related illness (2019). As per the global HIV/AIDS statistics – 2020 fact sheet, 26 million (25.1million – 26.2 million) people were accessing antiretroviral therapy as of the end June 2020. Since the start of the epidemic, an estimated 75.7 million and 32.7 million people have been infected with HIV and died of AIDS-related illness, respectively[18].

New HIV infections have reduced by 49% and 23% since their peak in 1998 and 2010 while AIDS related deaths have been reduced by 60% and 39% since their peak in 2004 and 2010 respectively[18].

As per estimation, around 5500 young women aged 15-24 years become infected with HIV every week and around 35% of women around the world have experienced some form of violence (physical/and sexual) by a partner or by non-partner at some time in their lives[18].

2.2 Indian scenario

The first case of HIV infection in India was identified in Chennai in 1986. Thereafter the first case of AIDS was seen at Mumbai. India's fight against HIV/AIDS has already crossed more than three decades with the establishment of the National AIDS Control Programme in 1992, comprehensively covering the entire prevention and control aspects of HIV/AIDs. National AIDS control organization (NACO) is the nodal agency for the same, which was setup under the Ministry of Health and family welfare, Government of India[19-20].

Over the different phases, following changes have been made in the programme. The focus has shifted from raising awareness to behavioural change and from centralized actions to more decentralized actions at the periphery to reach out to the ground level by involving community agencies, including NGOs and PLHA networks. With incorporating recent data analysis and scientific evidence, NACP is in fourth stage now. It has two prominent pillars - prevention services wing and care, support, treatment wing. The objective is to provide comprehensive coverage to PLHA and is aimed at reducing new infections by 50% from the 2007 baseline of NACP 3rd phase.

2.3 Recent actions

Government of India in 2016, reiterated the commitment at United Nations High-level meeting towards the goal of ending the AIDS epidemic as a public health threat by 2030 as well as UNAIDS (United Nations programme on HIV/AIDS) fast track targets for 2020 and (SDGs) sustainable development goals for 2030. India has already achieved MDG (Millennium development goals) targets in 2015 by halving the annual new infection rate and AIDS-related deaths and is now targeting the last mile to have robust and more effective sustained efforts towards HIV/AIDS services. The same were included in National Health Policy and National Strategic

Plan (NSP) – A seven-year plan for HIV/AIDS 2017 – 2024, and hence the coming years would be critical for early the achievement towards ending the game for AIDS. The goals would be Three Zeros – Zero new infections, zero AIDS deaths and zero discrimination[19-20].

The new fast track targets synonyms with UNAIDs targets, towards which NACO is focusing and include 75% reduction in new HIV infections and 90-90-90 strategy (90% who are positive know their status , 90% who know their status are on treatments and 90% who are on treatment experience effective viral load suppression) and by 2024, further accelerate the targets based on achievements[20].

In order to achieve these goals and end the AIDS by 2030, two landmark actions have been taken in 2017. These are HIV/AIDS Bill and Test and treat Policy, following the WHO guidelines.

2.4 HIV/AIDS Bill

India had First National AIDS prevention and control policy in 2002. With greater deliberations and concern towards PLHA, HIV/AIDS Bill was introduced in Indian Parliament and was passed in 2017 which criminalizes discrimination against PLHA. The Bill lists various grounds on which discrimination against HIV positive persons is prohibited which includes employment, education establishments, health care services, residing or renting property, standing public or private office and provision of insurance. The Bill also provides an environment for better care support and treatment by ensuring informed consent and confidentiality[21].

2.5 Test and treat Policy

It was in September 2015, WHO announced Global policy on Test and treat and later published guidelines in 2016. This was supported by recent scientific evidence of the ART use at the earliest point would keep PLHA alive and healthier and reduces the risk of transmission of the virus to a partner. India adopted this policy in 2017 and started ART to all PLHA as soon as possible after diagnosis irrespective of CD4 counts, clinical sage or age, at 536 ART centers across the country[22].

2.6 Epidemiology

As per Sankalak Status – National AIDs response – Second edition 2020[22], estimated HIV prevalence in India was 0.22% (0.17 – 0.29%) among adults aged between 15 – 49 years Keeping India among low prevalence country. As shown in Figure 2.6.2, Annual new HIV infections has been in decreasing trend since 2010 and 2019. Similarly, the annual AIDS-related deaths declined from 2010 and 2019, with nearly 66% decline, as shown in Figure 2.6.3. With respect to states/UTs, Maharashtra ranked first to have the highest number of new HIV infections (12%) followed by Bihar (12%), UP (10%), WB (6%), Gujarat (5%) and Delhi (4%). With 58.96 thousand AIDS-related deaths in 2019, AP has the highest number, followed by Maharashtra, Karnataka Telangana, UP and Tamil Nadu, as shown in Figure 2.6.5. Heterosexual (83.7%) mode of transmission remains the highest contributor for HIV source of infection Figure 2.6.1.

Figure 2.6.1 – Proportional distribution of HIV positive cases by Route of transmission (Self-reported) [22]

Legend:
- Not specified/unknown
- Parent to child
- Through infected syringe and needles
- Through blood and blood products
- Homosexual/Bisexual
- Heterosexual

2017-18 (N=1,80,900): 3.8, 4.4, 2.6, 0.8, 2.2, 86.3
2018-19 (N=1,77,823): 3.3, 4.2, 3.7, 0.7, 2.4, 85.7
2019-20 (N=1,67,967): 3.6, 3.8, 5.6, 0.8, 2.5, 83.7
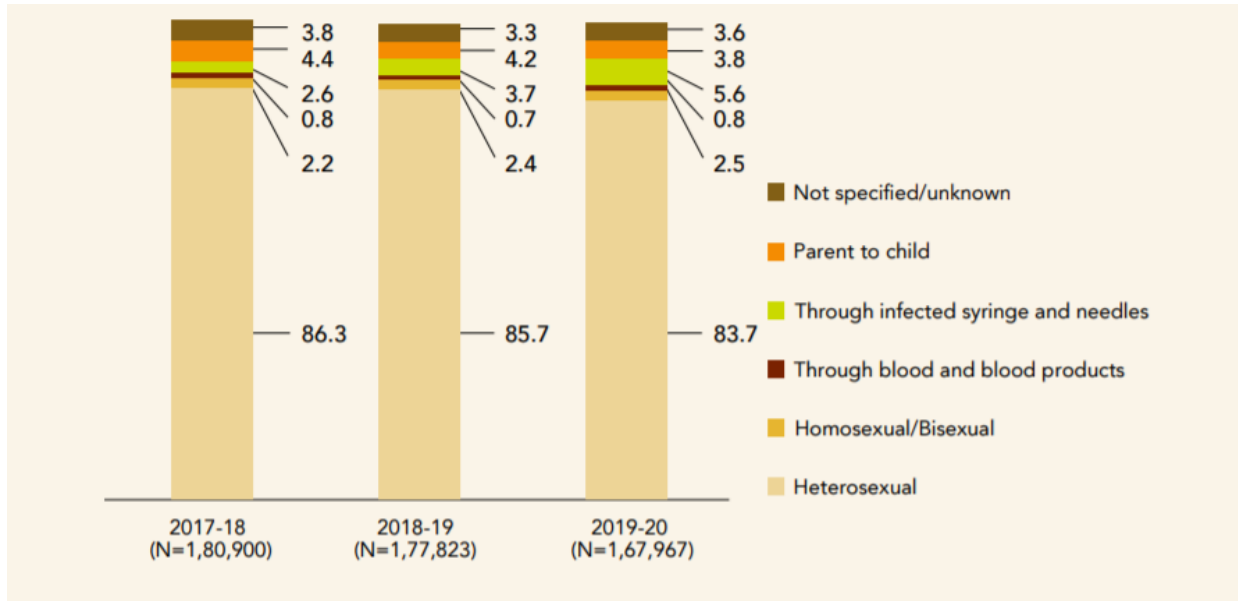
Figure 2.6.2 - Distribution of Annual new HIV infections [22]

37% decline between 2010 and 2019

Estimate — Lower and Upper bound
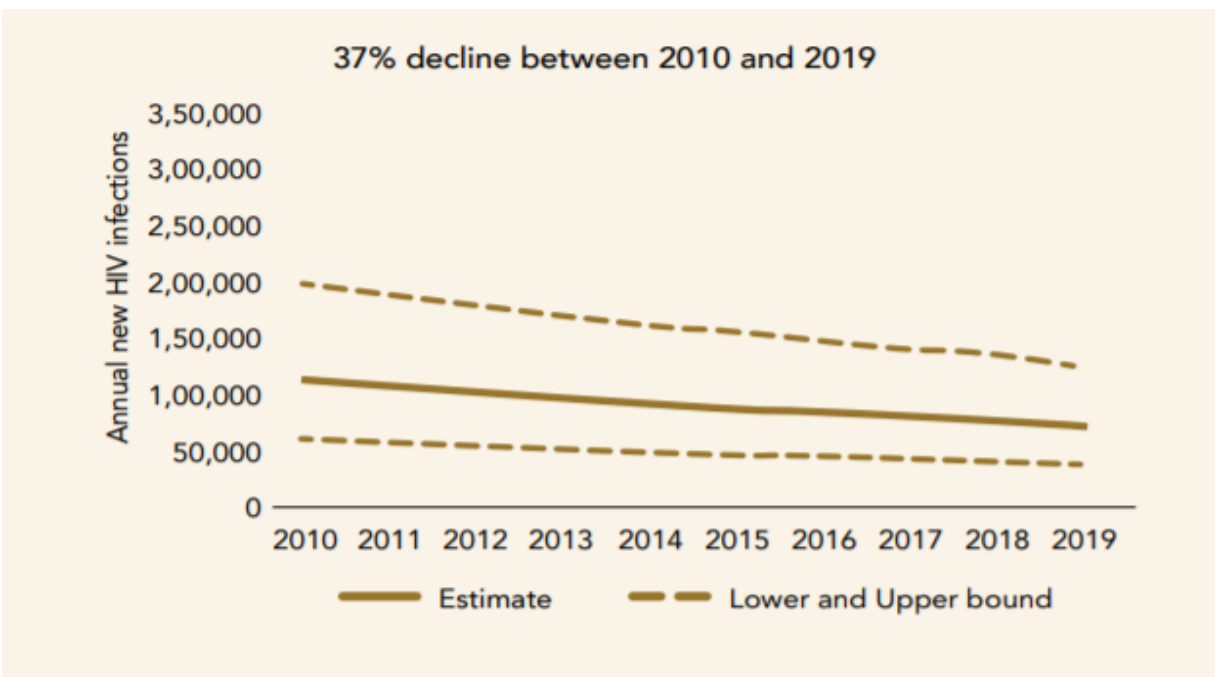
Figure 2.6.3 – Distribution of Annual AIDS-related deaths[22]

66% decline between 2010 and 2019
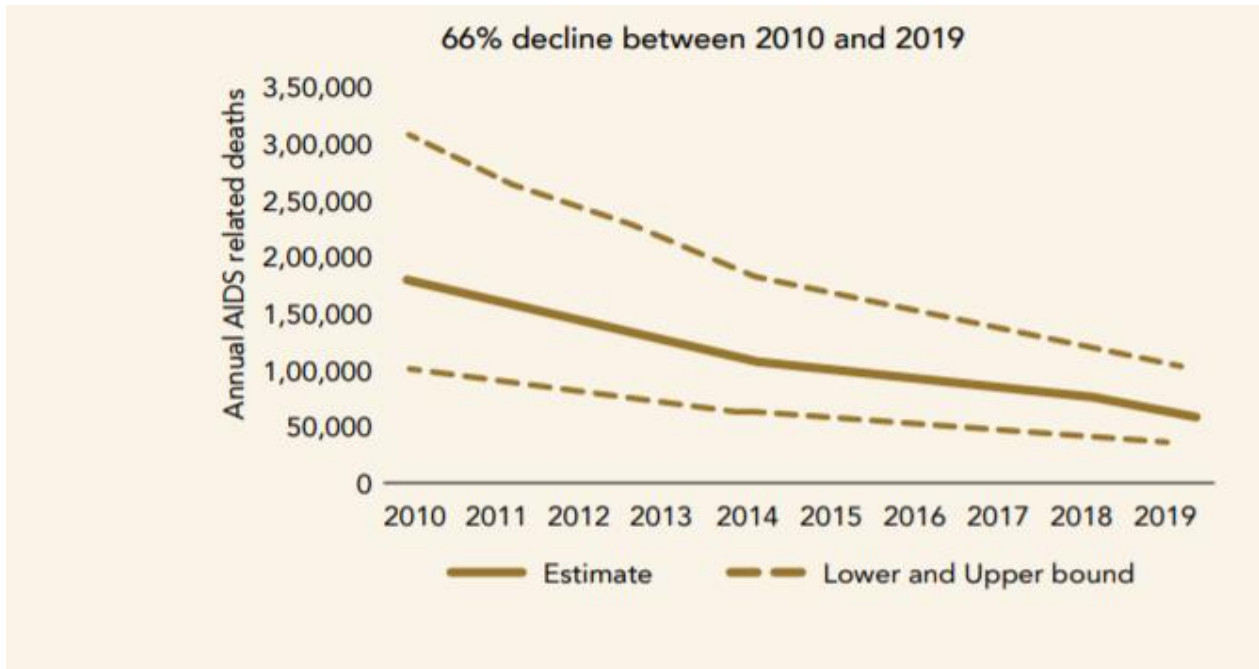
Figure 2.6.4 – State/UT – wise percent contribuion in total new infections (2019) [22]
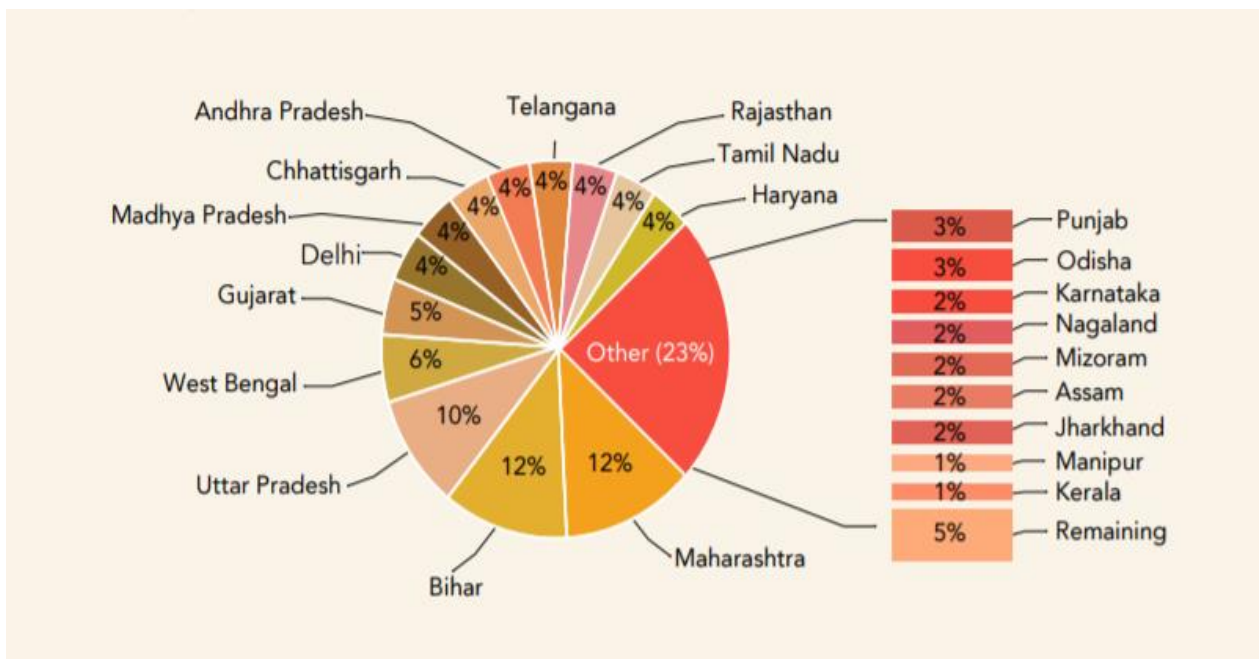
Figure 2.6.5 – State/UT-wise AIDS death in 2019 (in thousands) [22]

Figure 2.6.6 shows the latest progress on 90-90-90 targets at the National level. A total of 14.86 lakh PLHA were on ART as on March 2020. Concerning states , more than 80% targets were achieved by Chandigarh, Gujarat, Maharashtra, Punjab, Rajasthan and Tamil Nadu in 2019-2020.

Figure 2.6.6– Annual Progress towards 90-90-90 targets (2018-19, 2019-20) [22]
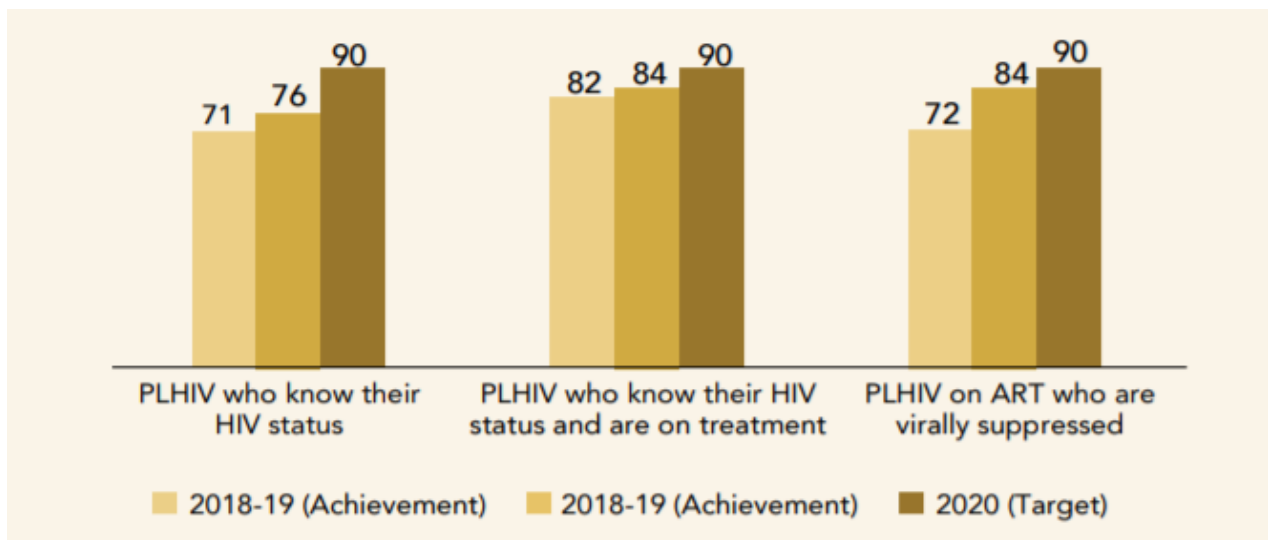
Since HIV/AIDs is influenced by many socio-economic factors and is not just a mere health issue, NACO has signed a memorandum of undertstanding with 18 ministries and department in order to have a multi-faceted and multi-sectoral target to various socio-ecionomic factors, but still, lot to be done for effective strategies for improving socio-economic conditions of PLHA[5]

2.7 Maharashtra - Statistics

Maharashtra is one of the high prevalence states wherein the adult HIV prevalence among 15-49 years group is 0.36 % (male – 0.38%, Female 0.33%) with an estimated 2.22 Lakh PLHA. Annual New HIV infections are 8,538 and Annual AIDS-related death 9,688 (2019) [22]. There is a 38% decline in annual new HIV infections since 2010 and a 72% decline in annual AIDS-related deaths. The highest prevalence is 5.20% among Hijra/Transgender, followed by 4.69% (Men who have sex with men) and 3.48% (Female Sex Workers). 89% of PLHA know their HIV status, 83% who know their HIV status are on ART and 87% on ART are virally suppressed. There are 91 ART centres, 188 Link ART centres and 44 Care support centres[22].

2.8 Initiation and management by ART

2004 was the landmark year, wherein Free ART was launched by the Government of India (GoI) to all PLHA through multi-layered service delivery mechanism of ART centres, LAC (Link ART centres), LAC Plus and CSCs (care and support centres). As of 2019, there were 553 ART centres, 1,327 LACs and LAC Plus and 310 (CSCs). Also, measures were taken in the form of Mission Sampark to track the Loss to Follow up patients[22].

2.9 Changing criteria for treatment initiation

As shown in figure 2.9, there was continuous change in guidelines for starting the ART over the period based upon the WHO recommendations and changing scientific evidence. In 2004 ART programme was started. In 2009, ART initiation was done if CD4 count below 250. Later on, in 2011, the criteria changed to CD4 count less than 350, in 2015, ART was initiated at less than 500, and finally in 2017, test and treat policy was accepted wherein all those who were positive were put on treatment irrespective of CD4 count and clinical stage. (Since our study data collection was started in 2015, we included PLHA who were newly started on ART when CD4 count was below 500) [22].

Figure 2.9 – Evolution of ART under NACP – Key milestones
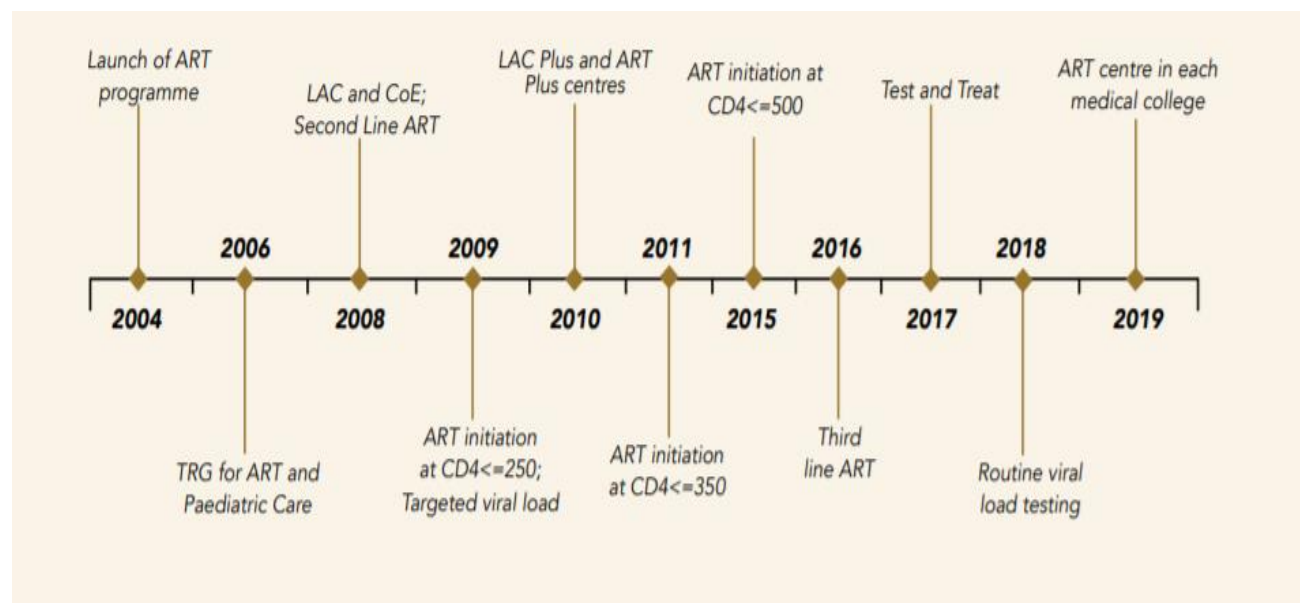
2.10.1 HIV and Nutrition

HIV/AIDS has a vicious relationship with Nutrition and may lead to malnutrition (Figure 2.10.1). While malnutrition weakens the immune system and increases vulnerability to opportunistic infections (OIs), which in turn cause symptoms such as anorexia and fever reduce food intake and nutrient utilization and increase nutrient requirements. Reduced food intake and poor nutrient absorption further weaken the immune system and hasten disease progression[23]. Hence both the factors must be dealt with utmost importance and measures to be taken for the same. In order to properly suppress and halt the infection, along with HAART, appropriate Goals to be directed to prevent malnutrition, improve health and nutritional status.

Figure 2.10.1 – Vicious cycle of malnutrition and HIV[23]
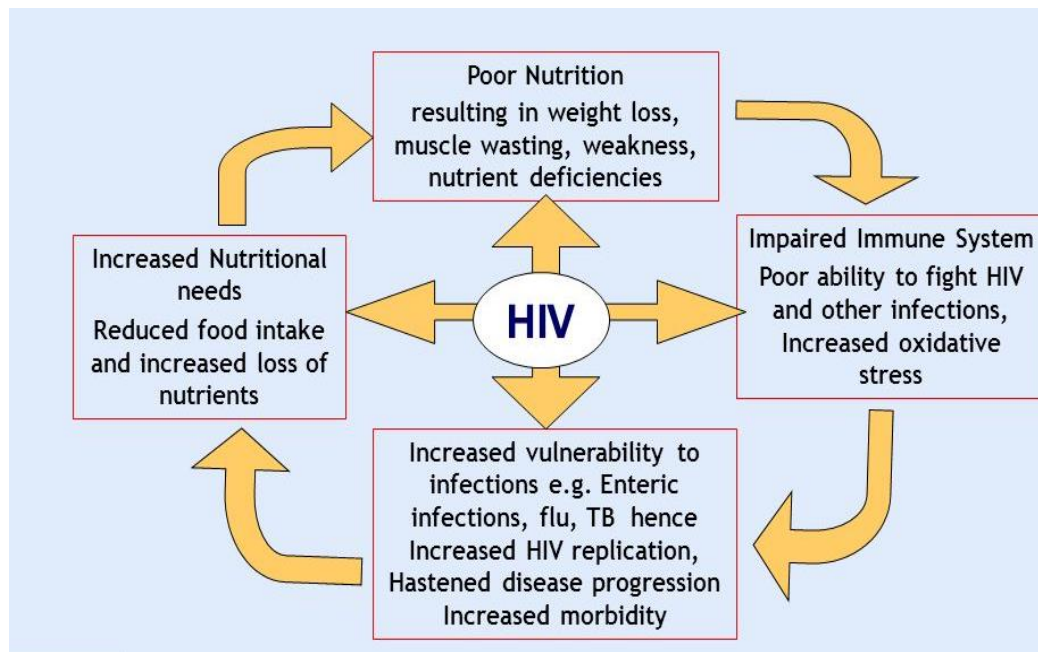
With the introduction of HAART, HIV/AIDS has become a chronically manageable disease rather than a life-threatening illness. However, there are variations in the disease course even after HAART introduction in developed nations and developing poor countries. While in developed

nations, the HIV related wasting with advanced disease has decreased and on the contrary, the prevalence of overweight/obesity is steadily increasing[24,25], but in resource-poor developing countries, with socio-economic factors and chronic food insecurity, newer infections are occurring in the backdrop of insufficient dietary diversity[26].

2.10.2 Effect of Nutritional Status on Immune system

Immune system response in HIV/AIDS has been across the spectrum of nutritional status ranging from malnutrition to obesity. Nutritional status through variety of pathophysiology affect innate immune activation ranging from altered mucosal barrier defences and microbiome in malnutrition to obesity led proinflammatory cytokine suppression by stromal vascular cells and hypertrophied adipocytes. At the same time, using endocrine mechanisms acting on T cell surface receptors, the T cell activation, proliferation and function has been modulated by nutritional status[27] (Figure 2.10.2.1).

As per the literature review, undernutrition and obesity are frequently seen among PLHA despite modern advances in HIV care, support and treatment and increased funding. While one of the major contributing cause of high levels of undernutrition among PLHA is due to pre-existing undernourishment and the HIV incidence largely overlaps with populations who are already undertaking low quality and quantity of food. One more important contributor is that due to HIV infection, PLHA undergo lower productivity leading to decreased income and increased expenditure in taking care of self and family[28].

Figure *2.10.2.1* – Conceptual framework Showing malnutrition as a cause and consequence leading to immune dysfunction[27]

Trends in Immunology
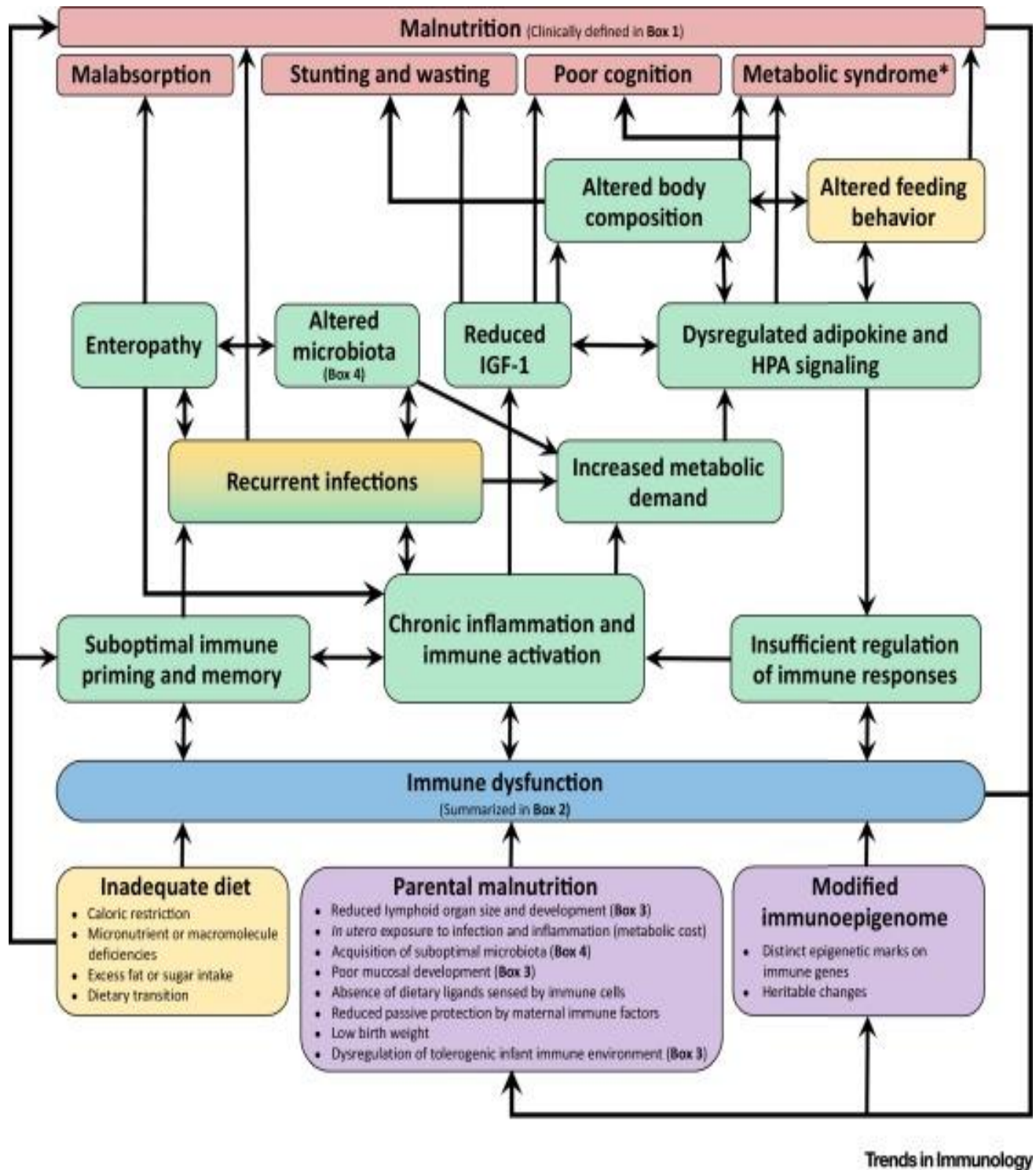
Different studies carried out across the world showed undernutrition level as low as 7.3% (Brazil), 10% (Zimbabwe), 11.1% (Iran), 12.3% (Dilla Ethiopia)[29,30,31,32] to moderate levels as 18.4% (Tanzania), 19.9% (Nepal), 22.9% (Senegal)[33-35] to higher levels as 23.2% (Demba), 23.6% (West Showa Zone), 25.2% (Bahir Dar), 42.3% (Ethiopia), 40% (India) [36-39.] However, there are lots of differences in these studies, showing wide variations based upon the sample size, type of study, socio-economic differences, socio-cultural differences, seasonal and country variations.

As per Alebel *et al.,* [40] in one of their meta-analysis studies, findings from 15 studies showed an overall 26% of undernutrition among PLHA after pooled data analysis with variations across different regions. Undernutrition was seen more among PLHA with CD4 counts <200, advanced disease, with symptoms like anemia and diarrhea. The authors suggested frequent assessments of nutritional status and measures to be taken thereof to tackle it.

Similarly, one more meta-analysis study by the same authors on 23 studies showed increased incidence of mortality among PLHA with undernutrition while higher risk of death was seen among severely undernourished PLHA as compared to mildly undernourished. They also concluded that undernutrition significantly increased the risk of developing tuberculosis among PLHA and further worsening the nutrition status[41].

On the other hand, overweight and obesity prevalence is also increasing with increasing HAART use and increased lifespan and making HIV a chronically manageable disease. HIV is associated with lipodystrophy which includes lipoatrophy (subcutaneous fat loss) and lipohypertrophy (increased fat cells) or both.

Fat alterations in PLHA as such are not fully understood as being multifactorial and complex phenomena. However, they are the result of direct effects of HIV Proteins and ART on adipocyte

health (Figure 2.10.2.1). The other superimposed factors include increased microbial translocation, genetic factors, increased tissue inflammation, accelerated fibrosis and adaptive immune milieu changes after infection[42].

As discussed above, the viral proteins secreted by HIV infected T cells and macrophages such as Tat, Vpr, Nef (Figure 2.10.2.2) affect proximal adipocytes and thus a cellular response is initiated. The responses include decreased adiponectin production, lectin, increased production of pro-inflammatory cytokines, mitochondrial dysfunction, fibrosis led by increased production of extracellular matrix.

Figure 2.10.2.2 - Effect of HIV on adipose cells[42]
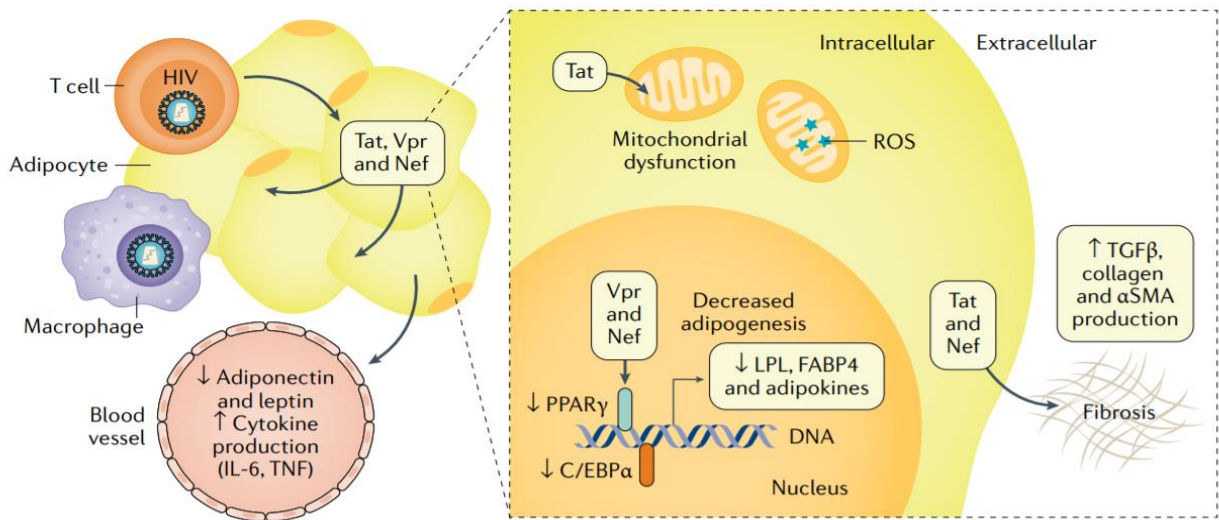
aSMA – Alpha smooth muscle actin,   C/EBPa, CCAAT – Enhancer binding protein
FABP4 – Fatty acid-binding protein4,   LPL – Lipoprotein lipase
ROS- reactive oxygen species,   PPAR – Peroxisome activated receptor,
TGF – transforming growth factor,   TNF – tumour necrosis factor

Figure 2.10.2.3 – HIV related and ART related adipose tissue alterations and dysfunction – Pathophysiology[42]

+++ A major effect, ++ a important effect, + a mild effect, + or – the effect is minor or absent
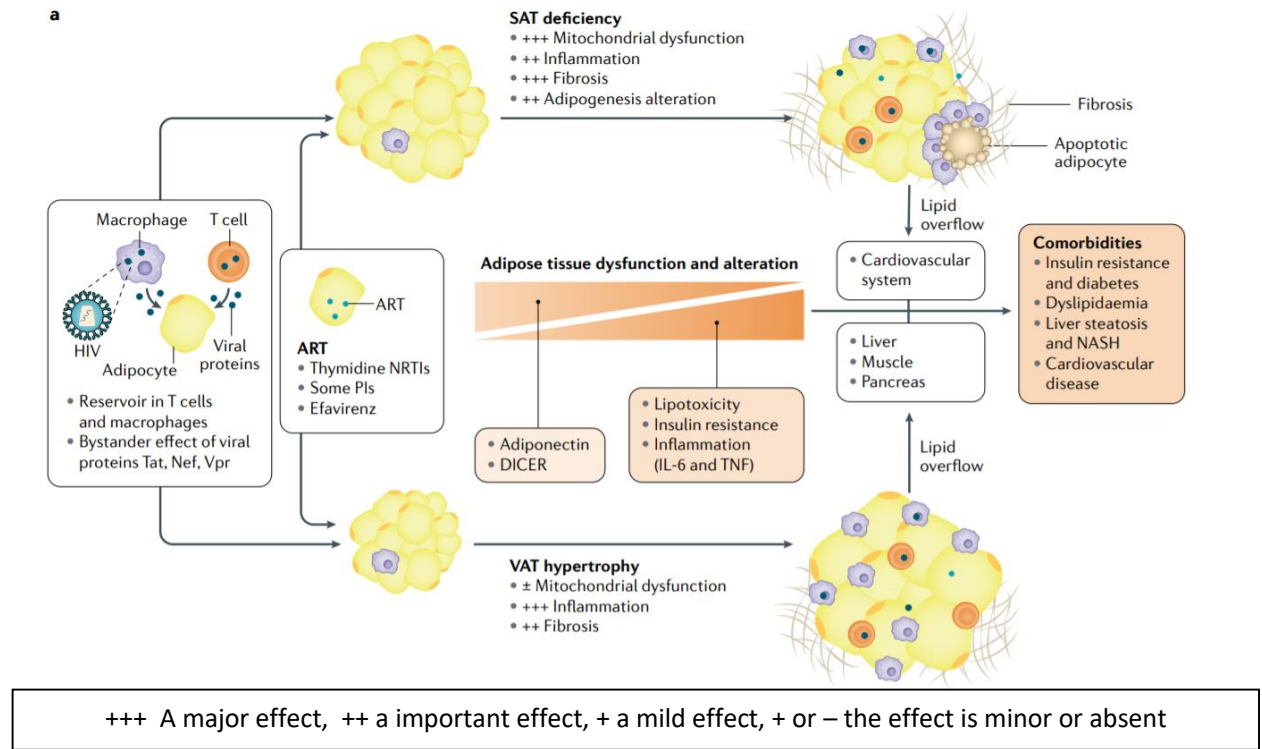
Figure 11 shows the pathophysiology where in VAT (Visceral Adipose tissue), and SAT (Subcutaneous adipose tissue) alterations take place among PLHA. These are due to two reasons – one HIV related and other ART related. HIV related is due to HIV proteins secreted by HIV infected immune cells within adipose tissue, which exert bystander effects on proximal adipose cells. Different ART drugs exert different effects with overall affecting adipose tissue. In SAT – a profibrotic, proinflammatory and anti-adipogenic environment is created as a result of adipose tissue stress and dysfunction which lead to insulin resistance and storage deficiency and then to lipid overflow drive. As a result of this SAT deficiency with VAT hypertrophy – ultimately leads to lipotoxicity and then showing the path for lipid accumulation in the liver, heart, muscles, vessels

and pancreas and also leads to type 2 diabetes mellitus, atherosclerotic cardiovascular disease, non-alcoholic steatohepatitis (NASH) and liver steatosis.

Figure 2.10.2.4 – Fat redistribution in HIV infected individuals as compared to lean and obese non-infected individual due to alterations of immunity in adipose tissue[42]
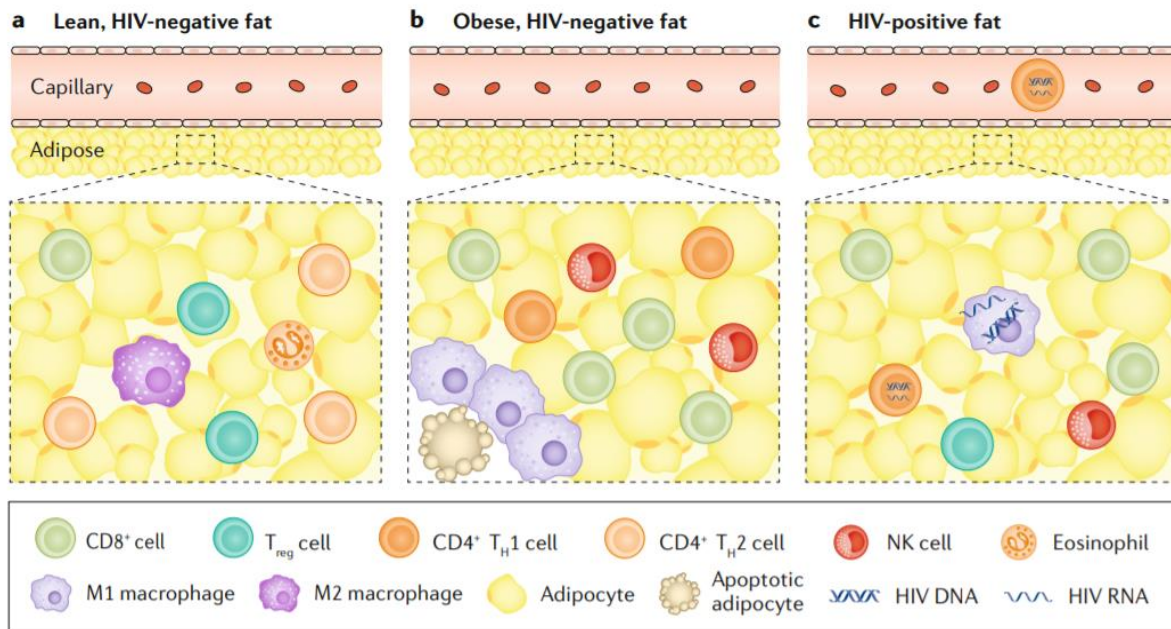
As shown in Figure 2.10.2.4, in lean individuals, adipose tissue is mainly adipocytes and stromal vascular cell fraction with CD4 T cells predominate and are polarized towards T helper 2 (Th2) cell cytokine profile. In obese individuals, adipose tissue is mainly hypertrophic and more heterogeneous. Adipocytes with CD8 T cells predominant and CD4 T cells are polarized towards T helper 1 (Th1) cell cytokine profile. In case of HIV positive (non-obese) persons, irrespective of presence of clinically apparent lipodystrophy, adipose tissue poses several similarities with obesity people. There is also a marked presence of CD8 T cells and presence of latently HIV infected CD4 T cells capable of producing viral proteins, and RNA virus. Thus, with the continued increase in overweight/obesity, PLHA lifespan, health span, and quality of life will be affected due to fat

alterations[42]. Therefore, there is a need for continued investigation and monitoring on factors responsible for malnutrition among PLHA.

As per review of the literature, various studies have shown a varying prevalence of NCDs risk factors among PLHA, but still, many regions lack an appropriate estimate of the problem. In a prospective study carried out by Dutta et al., [43], 79% of PLHA had higher insulin resistance, truncal fat, body fat and higher trunk-limb fat ratio and had one of the dyslipidemic abnormality. The BMI, truncal fat percentage and HIV duration were significant predictors for dyslipidemia. Along with that, central obesity and dyslipidemia were also associated with insulin resistance and hyperglycemia, leading to metabolic syndrome.

In another study by Mariz CDA et al., [44] the prevalence of overweight/obesity was 32.1%, while thinness was just 8.8%. Age above 40 years and diabetes were associated with obesity while no long-term partner, smoking, presence of opportunistic infections, anaemia and less albumin levels were associated with thinness. The authors suggested for targeted interventions along with lifestyle changes for healthier life among PLHA.

In another study carried out by Malaza A et al.,[45] obesity and hypertension were significantly associated with sex, age, HIV and ART status, and obesity was more significant risk for hypertension in men than in women.

Mathebula et al.,[46] showed that in an average duration of starting ART of 3.6 years, the prevalence of overweight increased from 18.1% to 21.4%, and obesity increased from 11.5% to 19.6%. Females had a higher prevalence of abnormal waist circumference (42.5% females, 4.4% males). The authors concluded a very high incidence of NCDs among PLHA on ART and suggested urgent interventions. In one of the multinational cohort studies on PLHA, Mave V et al., (NCD 6) showed

with an average duration of 48 weeks, overweight/obesity increased from 27% to 37%, and underweight decreased from 8% to 3%. In overweight/obesity, the weight gain predicted increased inflammation. while in underweight, weight gain predicted reduced inflammation.

2.10.3 Dietary diversity

It is a quantitative measure of food consumption that reveals household access to a variety of food, it reflects the nutrient adequacy of the diet. Dietary diversity is a quantitative number of food groups that is used extensively as a method of assessing the variety and nutrient adequacy of diets. It's the most significant challenge for PLHA to achieve an adequate quantity and quality of food and nourishment to fulfil basic needs for wellbeing, growth and development. Diversified diet includes foods from vegetables, fruits, grains, and animal source, foods that provide a balance of nutrients needed for healthy growth and development. Thus, undiversified food and malnutrition are public health concerns worldwide. Chronic patients like HIV/AIDS patients especially those living in developing countries, are at high risk because of consuming low quality, monotonous food leading to micronutrient and macronutrient deficiencies[47].

Non-diversified food reduces physical, social, cognitive, reproductive and immunological capacities and thus, has negative consequences on PLHA health, wellbeing and development. The extent to which dietary diversity are met will determine the quality of care and treatment facilities being provided to PLHA by the health care providers and which in turn will improve the quality of life of PLHA[47].

As per the literature review, different studies have shown different levels of dietary diversity across the world. As per the study carried out by Tesfaw A et al.,[47] revealed 29.5% of HIV patients had got inadequate dietary diversity which was lower than study carried out at Jimma (44.2%), Kenya

(37.7%), Eastern Uganda (41%) and Ethiopia (61.2%). In this, 96.1% and 81.7% of study participants had consumed starch and legumes respectively during the 24-hour recall method while meat, milk and milk products were least consumed. Those participants who had media exposure, nutritional counselling got more dietary diversification than compared to others.

Similarly, in a study carried out by Weldegebreal F et al.,[48] 28.7% PLHA had low dietary diversity scores. Participants with ART more than two years were two times more likely to have better dietary diversity than less than a year ART PLHA.

Another study carried out by Markos M et al.,[49] showed a very high percentage of participants having inadequate dietary diversity (60.1%), and factors responsible for the same were lack of dietary counselling, less monthly income, female and ART duration less than a year. Low dietary diversity being a major nutritional problem, they suggested exceptional attention in nutritional care and appropriate counselling and support during early initiation of ART.

Woldemariam AT et al.,[50] study showed 58.8% of study participants had low individual dietary diversity score. Self-employed, lowest wealth quintile, daily labourer, PLHA with ART duration less than one and half year and those who were on cotrimoxazole prophylaxis were significantly associated with lesser dietary diversity, and authors recommended that measures be taken to improve employment status and animal food consumption.

Similarly, Sirotin N et al., [51] in their study on PLHA women, showed 46% had food insufficiency, 43% had poor dietary diversity and 15 % low BMI. Both were associated with low education and low income. Food insufficiency was associated with alcohol intake. Nutrition was inversely associated with HIV infection, and surprisingly, it was not correlated with dietary diversity nor

food insufficiency. Hence authors concluded that low BMI might not be an adequate screening tool to measure food insufficiency.

Taye K et al., [52] in their study on dietary diversity among Adult PLHA, showed a poor dietary diversity score in 71% of participants. Male individuals were 57% less likely to have poor dietary diversity compared to females. Similarly, adults who were separated from husband/wife were 68% less likely to have poor dietary diversity than widowed adults and authors recommended that the administrative authority and NGOs working in the HIV field should consider employing women and provide options for income-generating schemes for HIV patients.

Martin-Canavate R et al., [53] on dietary pattern study on children revealed that (33.2%) majority of study participants were stunted, 10% were overweight/obese and 3.3% were wasted. The consumption pattern showed that children consumed less of vegetables and fruits but more of cereals and eggs with more fat/sugar diet and less of dietary diversity. On analysis, it was seen that being female, young age and under-care significantly increased the chances of consuming healthy diet. The authors therefore recommended that dietary pattern assessment periodically gives us the clue regarding interventions needed to design a healthy lifestyle.

2.12 Social Determinants of Nutritional status among PLHA

HIV infection affects various domains of patients' life. He faces enormous challenges, including changes in intimacy, social status loss, job loss, role, financial resources and discrimination. Accordingly, empirical evidences have shown that food insecurity, Job/Income security, Quality of life, WaSH practices, cooking, and eating habits are closely associated with malnutrition among PLHA and therefore, health care providers, program planners should be aware of struggles faced by HIV patients and provide them multidimensional support[54.]

2.13 Food insecurity

Operational definitions may vary with different organizations for food insecurity. The most comprehensive definitions describe food security as the limited or uncertain availability of nutritionally adequate, safe food or the inability to acquire personally acceptable foods in socially acceptable ways[55].

The association of Food Insecurity and HIV/AIDS is best described as "Syndemic", which means epidemics that coexist and perpetuate each other. The ideal country showing this situation is Sub Saharan Africa, where both the prevalence of HIV and prevalence of undernutrition is highest in the world. Thus, geographic overlap of both can be seen in this country. Second would the Asia, where the dual epidemics are marked with the highest number of undernourished people and an increasing number of HIV cases. Even in developed nations, such a dual situation is seen in a specific population. Moreover, it's a vicious cycle relationship between food insecurity and HIV as both increases the risk and outcomes of each other at all levels, including at individual level, community level and population level. HIV affects PLHA nutritional status and constraint access to food. By reducing household labor resources, depleting income and assets and interrupting intergenerational knowledge transfer, HIV leads to household food insecurity. The morbidity and mortality due to HIV also leads to reductions in agricultural production and economic development. Through behavioral, nutritional and mental health pathways, (Figure 13) food insecurity leads to adverse clinical outcomes, increased risk of transmission, inadequate health care utilization, poor ART uptake, non-adherence to ART and poor immunologic and virologic response (Figure 2.13.1). In view of the above, there is always a need to integrate food security and nutrition among HIV programs catering for care support and treatment[56].

Figure 2.13.1 – Conceptual framework for food insecurity and HIV/AIDS[57]
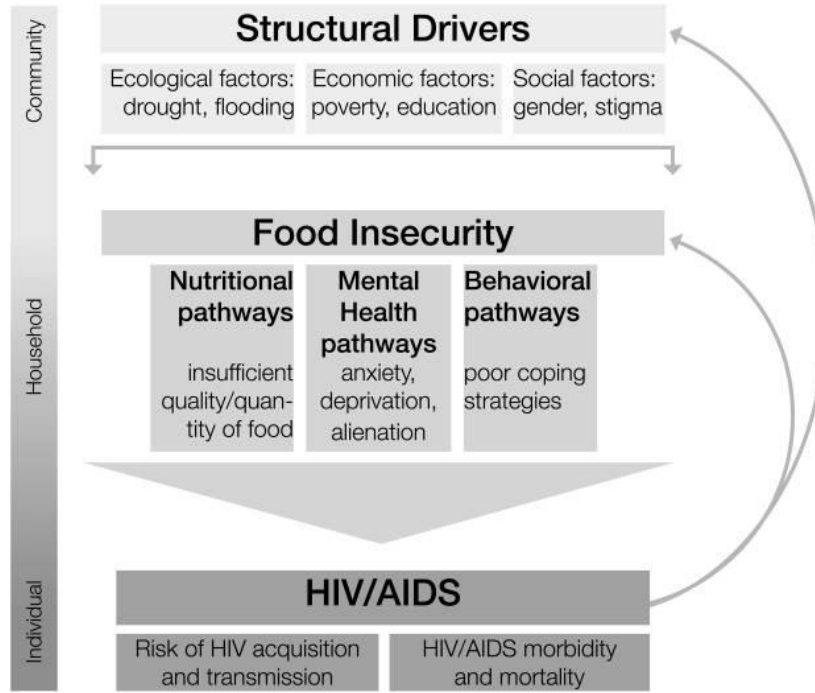
Figure 2.13.2 – Three pathways of food insecurity and HIV/AIDS morbidity and mortality[57]
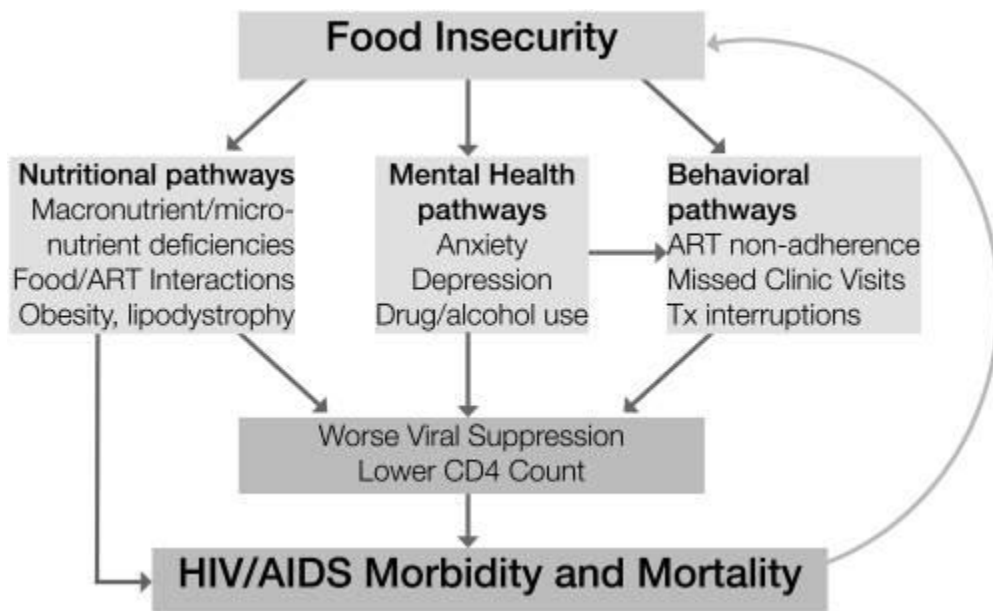
Food insecurity is known to worsen viral suppression and lower CD4 counts using three pathways (as shown in figure 2.13.2) [57], thereby affecting HIV/AIDS morbidity and mortality. Food insecurity leads to undernutrition and micronutrient deficiencies, low albumin. All these are known to increase the progression of the disease and shown to predict opportunistic infections. With increasing morbidity, disability, there will be employment difficulties and hence procurement of food. On the other side, food insecurity also has a negative effect on Health through obesity and poor diet quality. The probable mechanisms, as proposed by researchers, are driven by substitutions of cheaper, energy-dense foods, over-consumption during food availability periods and compensatory changes in metabolism. Studies carried out in developed nations showed that PLHA with food insecurity has been associated with obesity, hypertension, diabetes, and self-reported dyslipidemia[58,59,60].

A review of literature has shown wide variations in food insecurity levels among PLHA across various countries. A recent study carried out by Oluma A et al., (61) showed food insecurity among PLHA to the extent of 68.8% with mild (23.32%), moderate (29.09%), severe (16.35%) grade. Anaemia, cigarette smoking, opportunistic infections, marital status, educational status and inadequate dietary diversity were all significant predictors of food insecurity.

Similarly, in a study carried out by Gebremichael DY et al., [39], food insecurity among PLHA on ART was 35.2% and authors suggested effective cross-sectoral integrated programs to tackle malnutrition and food insecurity. Even in developed countries like the US, Australia and Canada, studies have shown a significant percentage of food insecurity among PLHA, highlighting the need

for food, cash and socio-economic interventions to overcome food insecurity and improve the quality and health status of PLHA[62-64].

To halt the progression of HIV/AIDS, there are implications for research, policy and practice to control effects of food insecurity effectively. Concerning research, longitudinal research studies need to be carried out to unpack the relative impact of each pathway on health outcome as discussed above. Priority interventions are required that target structural drivers of food insecurity and HIV (Agricultural factors, economic factors and social factors). Policymaking should focus on food security and HIV as these are linked issues that demand greater attention and funding[57].

2.14 Quality of Life (QoL)

With more advances in HIV science and more use of HAART, HIV has become a chronically manageable disease. With this longevity in focus, Quality of life has emerged as an essential indicator of health status among PLHA. QoL mainly focuses on the sense of well-being and includes satisfaction and happiness in larger terms[65]. As per World Health Organisation, QoL has been defined as Individual perceptions of their positions in life in the context of culture and value systems in which they live and in relation to their goals, standards, expectations and concerns[66]. The QoL, HIV and nutrition are interconnected to each other. Despite HAART, if the disease progresses, then it is usually associated with low nutritional status and impaired immune system leading to opportunistic infections and increased mortality and morbidity. Malnutrition and HIV have thus negative influence on each other and thereby leading to impaired QoL. Nutritional status affects the physical and mental health and thereby affect QoL. Apart from these, a better nutritional status assists in symptom management, improve ART absorption, ART tolerance and thus HIV progression is delayed[67]. It is well-established theory in chronic diseases that nutritional status

improves QoL, but in the case of HIV, it still must be explored more. Although few studies have shown good QoL in PLHA with good nutritional status and lower anthropometric measurements leading to poor QoL[68].

Although better QoL in PLHA is associated with many factors as per review of literature, the impact of HIV on QoL has been broadly divided into four domains (Physical domain, psychological domain, social domain and environmental domain) as described in figure 2.14.

Figure 2.14 – Four major domain for QoL in HIV/AIDS[65]

The physical health domain assesses the impact of disease on the activities of daily living, dependence on medicinal substances, fatigue, restricted mobility, presence of pain and discomfort, sleep and rest, a lack of energy and initiative, and perceived working capacity.	The psychological domain assesses the patient's own thoughts about body image and appearance, negative feelings, positive feelings, self-esteem and personal beliefs. It also effects positive self-concept, higher cognitive functions, body image, spirituality, anxiety, suicide and depression	Social domain assesses personal relationships, social contacts, social support and sexual activity	The environmental domain assesses areas such as freedom, quality of home environment; physical safety and security, financial status; involvement in recreational activity, health and social care quality and accessibility

2.15 Food Insecurity, Common mental disorders (CMD) and QoL

As per the review of literature, including meta-analysis studies in both low-income countries and developed nations, food insecurity has been associated with higher Common Mental Disorders (CMDs) (Figure 2.15). Poor access to adequate food and nutrition, leading to food insecurity also leads to poor QoL. Even studies in Uganda[69] also showed severe food insecurity leading to lower QoL independent of dietary quality. Studies from Sub-Saharan Africa and India also showed lower QoL associated with CMDs[70-71]. Similarly, Vu GT et al., [73] carried out global research on QoL with HIV/AIDS showing region wise and cultural wise variations of QoL among PLHA. Based on his analysis of all studies across the world, QoL has been used in assessing harm reduction strategies, clinical treatment and prevention Programs across the globe, vary widely after knowing the significant associations of QOL and effectiveness of HIV programs.

Figure 2.15 – Inter-relationship between Food Insecurity, CMDs and QoL[74]
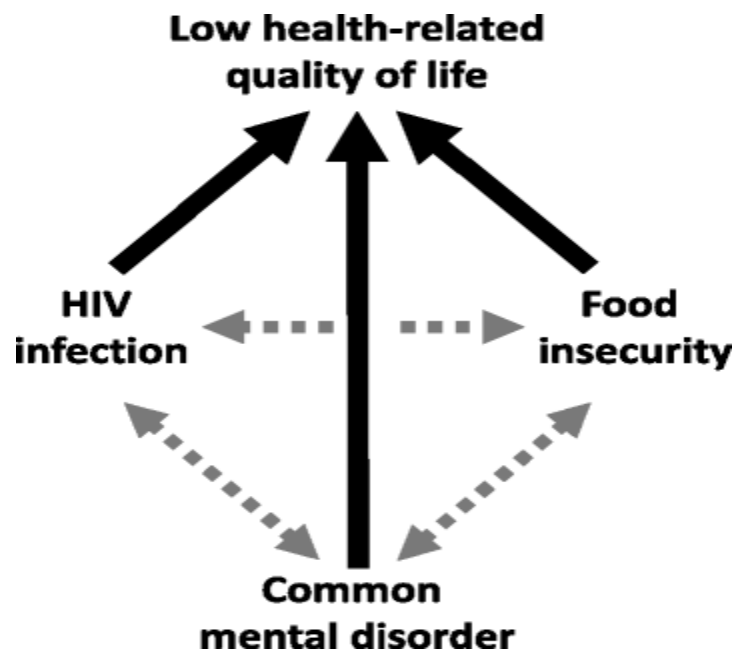
As per the literature review, a vast degree of variations in QoL on PLHA is seen across the world. In a study carried out by Palermo et al., in Uganda, 66% of PLHA households were classified as severe food insecure, while PLHA with low, medium and high dietary diversity was 15,76 and 8, respectively. Mean mental health scores and physical, mental scores were 1.7 points lower and 1.5 points lower, respectively, among PLHA with severe food insecurity. Similarly, mean mental health scores and physical mental scores were 3.6 points and 2.8 points higher, among PLHA with high dietary diversity. This indicated food access and quality diet are associated with better QoL[75].

In another study carried out by Tesemma et al., in southern Ethiopia, 47.1% were having poor QoL. Good QoL was associated with the absence of depression, a recent increase in CD4 counts, social support, normal BMI and no perceived stigma. The authors recommend structured social support systems to maintain their psychosocial health and nutritional support for better QoL[76].

Tesfaye M et al., study showed 38.7% severe food insecurity among PLHA, and it was associated with lower QoL along with higher CMD symptoms and being underweight[77]. Osei-Yeboah J et al., in Ghana showed only 11.39 % with poor QoL, and factors favouring Poor QoL were perception of health, sexual activity, patient occupation and state of the disease[78].

An observational study in India by Anand D *et al.,* [79] showed PLHA with lower BMI also had poor QoL. Various other studies by Tesfaye M *et al.,* [77], Shriharsha C *et al*[80], and Anuradha *et al.,* [81] emphasized the importance of QoL among PLHA which otherwise would severely affect their mental wellbeing and PLHA can go into depression and thus a vicious cycle to start with poor nutritional status, depression and QoL.

In one of the studies carried out by Thomas R et al., [83] the famous HPTN 071 trial, when compared to PLHA on ART for more than five years, HIV negative individuals Health-related QoL scores didn't differ significantly, but Health-related QoL scores differ significantly among PLHA with less than five years ART and HIV negative individuals. The study also showed HIV positive individuals with HIV status unknown had better QoL and were like HIV negative ones and vice versa.

2.16.1 WaSH Practices

To maintain the dignity of PLHA health and life, WaSH practices are very much essential. The term WaSH refers to the following -

Water – access to good quality and quantity of water.

Sanitation – Safe handling and disposal of human excreta including faeces, urine, menstrual blood, sputum and sweat, management of wastes include trash, wastewater, stormwater, sewage, and hazardous wastes and control of disease vectors including mosquito and files.

Figure 2.16.1 – WaSH and animal factors contributing to diarrheal illness[83]

Feces from Infected Host	Exposure Pathways	Fecal-Oral Transmission	Infection of New Host
• Companion animals • Livestock • Wildlife • Synanthropic rodents • Humans	• Food • Fluids • Floors/Fields • Fur/Feathers • Fingers • Fomites • Flies	• Consumption of contaminated food or water • Accidental ingestion through contact with contaminated soil or items	• Diarrheal illness and/or other symptoms of enteric disease • Asymptomatic infection

2.16.2 Hygiene practices – including hand Washing in particular

Water Sanitation and Hygiene practices always have been neglected among HIV/AIDS programs thinking HIV is not a water-borne disease, nor it spreads by poor hygiene-related diseases like diarrheoa, cholera and typhoid etc, thus having no direct link between HIV and WaSH (Figure 2.16.1). On the contrary, HIV and WaSH services have robost bearing on each other. HIV/AIDS is an immune-compromised state where in chances of getting opportunistic infections through water and food are very high. It is estimated that diarrhoea rates are 2-6 times and persistent diarrhea two times higher among PLHA than in HIV negative persons[84,85]. Accordingly when PLHA become bedridden, fragile and incapacitated, they require effective WaSH practices[86] because these practices involve frequent washing of infected linen, clothes, clean hygienic environment, proper segregation and safe disposal of human wastes including faeces, urine, menstrual blood, sweat, wastewater and sewage drainage system. It involves effective mosquito

and flies control measures too. Hand Washing is also very essential for PLHA as handwashing is most appropriately known as "Do it Yourself Vaccine" and has been effective in reducing the diarrhoea incidence to less than 42-44% if practised effectively[87,88].

Despite evidence of priority link between HIV and WaSH practices, most countries have not integrated HIV and WaSH practices in HIV programs. In a study carried out by Yallew WW et al.,[89] 67% of PLHA households had poor hygiene practices. There were significant associations between water status and diarrheoa, sanitation status with education and latrine availability, hygienic practice with hand washing machine availability and economic reasons. Even as latest as 2020, a study conducted by Tessema RA et al., showed that only 68% PLHA had good hygiene practices, only 37% had basic water facilities, only 58% of them acquired recommended quantity of safe water for drinking. The authors also analyzed the adjusted prevalence ratio, where two-week prevalence of diarrhea was less by 8%, 7% and 5% in PLHA who practiced good hygiene, washed their hands with soap and consistently used sanitation facility. The authors have asked for effective integration of adequate WaSH services to HIV/AIDS program to increase QoL of PLHA[90].

2.16.3 PLHA essential hygiene practices[91]

Water Hygiene and Handwashing: - Both good quality and adequate quantity of water is essential for PLHA' hygiene. At some places, especially in rural areas, the required quantity nor quality of water is not available making PLHA vulnerable to water-borne and hygiene-related illness. The public water should be treated with affordable techniques like water chlorination, filtration, proper boiling, solar disinfection, and reverse osmosis/ultraviolet radiation. Boiling is most used, while variety agents can be used for chlorination like bleaching powder, calcium hypochlorite in terms

of powder, liquid or gas[85]. Latently solar disinfection is coming up very well which uses ultraviolet A radiation which is abundantly available, and it doesn't affect the taste, colour, or odour of water as chlorination does. Handwashing too, is most important for PLHA, which helps him to prevent contracting various food and waterborne disease, including respiratory illness. PLHA should be aware of steps of handwashing, methods of handwashing, timing and frequent routine indications of handwashing for effective control[91].

Sanitation Hygiene - Ideal sanitation setup for PLHA would the infrastructure with safe, reliable, easily accessible, clean, private, weather protected, ventilation adequate, minimum smells and minimized the risk of spreading the sanitation-related diseases. Hygiene sanitation ideally required proper segregation and handling, disposal of human excreta including faces, urine, menstrual blood and sweat, efficient management of wastes like wastewater, sewage and hazardous wastes and prevention and control of vectors such as mosquito and flies etc[91].

Makaudze EM et al., in his research[91], supported by the Water Research Commission in South Africa, demonstrated perceptions of PLHA WaSH practices in three different regions representing rural, peri-urban, and urban slums. The study showed, 34% use to wash their body regularly, 32.2% wash their hands before eating and < 10% use to wash hands after toilet use and showed severe lack of awareness during critical times in slum areas. The results showed lack of enough knowledge on handwashing practices and lack of knowledge on the extent of vulnerability to opportunistic infections by PLHA. The authors suggested integrating of WaSH practices and strong health campaigns in HIV/AIDS programs and improvement in hygiene practices which would provide "Nightingales moment" to PLHA.

2.16.4 The New 90-90-90 water - sanitation-hygiene indicator

Makaudze EM et al., [91] introduced a **new 90-90-90 water - sanitation-hygiene** indicator scoreboard like UNAIDS 90-90-90 ambitious targets to end the epidemic of AIDS. The new 90-90-90 water – sanitation-hygiene indicator interprets as 90% of the population have access to clean water, 90% of them use safe sanitation and 90% of have hand washing facilities with soap, and water in the premises.

2.16.5 HIV/AIDS Programs – WaSH Interventions

After an extensive literature review, there is lots of information lacking concerning WaSH practices within the HIV/AIDS programme. However, few countries tried to implement WaSH interventions suggested in HIV/AIDS programme. But significant reason for non-implementation was the non-availability of enough funds. Quintanilla WE et al., discussed in his article[92], about the three key WaSH interventions which could be integrated into Sub-Saharan Africa regions.

Drinking water treatment interventions: - Following interventions can be included in HIV Programs. Distribution of Water treatment solutions (Chlorine products), sand or ceramic filters, storages receptacles, training on solar disinfection of water, and educational or health promotional campaigns on household treatment and safe storage of water. Improved access to water supply also is necessary interventions which include focusing on upgrading the source of water like construction of wells, rainwater harvesting and others.

Hand Washing interventions which can be suggested are distribution of soaps, tippy taps, constructions and demonstrations of Tippy taps (handsfree device to hand WaSH in areas where

there is no running water), social marketing campaigns promoting hand Washing with soap and demonstrations of hand Washing with soap.

Sanitation interventions – Distributions of materials needed for latrine constructions, social marketing campaigns through sanitation promotions, subsidizing the cost of latrine building materials, Sensitization and health education on disposal techniques for menstrual blood, modifications of latrines with railing and ropes for PLHA with weak stamina and , ramps constructions to facilitate latrines access.

With Covid 19 Pandemic on the go, it is utmost necessary for the PLHA to ensure adequate WaSH practices. Governments at all levels should take steps to integrate all these WaSH interventions into HIV/AIDS programs, because its high time considering Covid 19 pandemic and PLHA are known to get more infections compared to HIV negative being immunocompromised. In-depth analysis of various studies showed Organizations are unable to implement these practices because of low funding. Hence Government or NGOs should actively considerate on these issues too and increase funding as well as undertake massive behaviour change communication (BCC) among PLHA.

2.17 Job insecurity

Job insecurity is a growing phenomenon, not only in PLHA but also among the general population considering high levels of temporary employment and unemployment. Because of decreased immunity and at times, decreased capacity to work, most PLHA on temporary disability struggle to overcome significant challenges that affect their ability to live independently, they have cited to reentry into working because it gives them financial security, enhanced self-esteem, the

opportunity to create a social support system and reduction of the family financial burden and increased social interaction[93].

Whereas for PLHA with long term disability and unemployment, various obstacles make them transition to reentry into employment very difficult. These challenges include concerns of possible loss or change in health benefits, fear and anxiety over the possibility of disclosure and HIV related prejudice and discrimination and relative lack of education/skills, which make them not confident of joining back the employment. But these PLHA do also think of income insecurity because of which they can even worsen their health status and particularly if they are the only income source in the family, then health including the life of other family members, may become more complex. In such cases, PLHA may require additional assistance for reentering the workforce such as job preparation, training and job hunting. Government and institutions should start employment services including referrals, job listing, interview skills, counselling, workshops on vocational opportunities and educational focus so that PLHA can motivate themselves for rejoining the workforce and contribute to their self, family and community at a large[94].

A review of literature gave us an in-depth view of job insecurity and factors associated with it. Rueda S et al., [94] on his analysis of job security, on physical and mental health, showed better mental health related QoL among PLHA with employment with secure jobs than compared to unemployed. However, with respect to insecure employment, it was not associated with a higher mental health scores than compared to unemployment. The above finding holds true for men while in women being employed didn't have any additional health benefits, although it was associated with higher mental health quality of life. The authors finally recommended that the Government should promote employment policies for PLHA, which promote job security for them so that their income stability and mental health benefits increases.

Dray-spira R et al., [95] in their study on HAART effect on employment loss showed that during the median of 2.5 years, 18% employment loss was there among PLHA receiving HAART. On further analysis, it was found that non-permanent job, poor accommodation, female gender were primary reasons for employment loss. In contrast, PLHA on high employment position had less chances of failure. Other factors responsible for job loss were updated viral load > 10,000 copies/ml and hospitalization in the last six months, CD4 counts less than 350/mm3 and chronic morbidity. These factors have been faced by most HIV positive patients during their course of illness, and job security and income security become the main pathway where they get failed. Hence Job/income security is most important not only for a PLHA but also for any normal human being to maintain his life efficiently. The authors have advised for social interventions to prevent HIV infected patients from losing their job from the earliest stage of the disease.

The above findings have exaggerated many times during the Covid 19 pandemic wherein Government announced lockdown had shaken up PLHA, with the apprehension of Job insecurity, income insecurity, availability of medicines and most important, contracting the Covid 19 infection itself. The pandemic situation is an excellent guide for program managers to think on various parameters which have been neglected in a minor way, especially in concern with nutritional status and socio-demographic factors responsible for malnutrition including food insecurity, job/income security, WaSH practices and over the quality of life thereof.

As per Marbaniang I et al., [98] in this latest study during Covid 19 pandemic in Pune, India, regarding anxiety among PLHA found that overall prevalence of generalized anxiety was 25% among PLHA and main concerns were both health-related as well as health unrelated, but would worsen with the worsening pandemic. The problems were associated with immediate effects and imminent future, lack of social and financial support (Figure 2.17) and indifferences to

circumstances secondary to Covid 19. One of the main results of anxiety would lead to non-adherence of HAART. With a high percentage of 25%, going into non-adherence would lead to far-reaching consequences for viral suppression, HIV transmission and antiviral resistance in the community. Hence all these factors play an important role, and as a health care provider we must investigate these factors and convince to the policymakers for more efficient HIV program giving coverage to all these factors.

Figure 2.17– The burden of anxiety among PLHA during Covid 19 Pandemic[96]
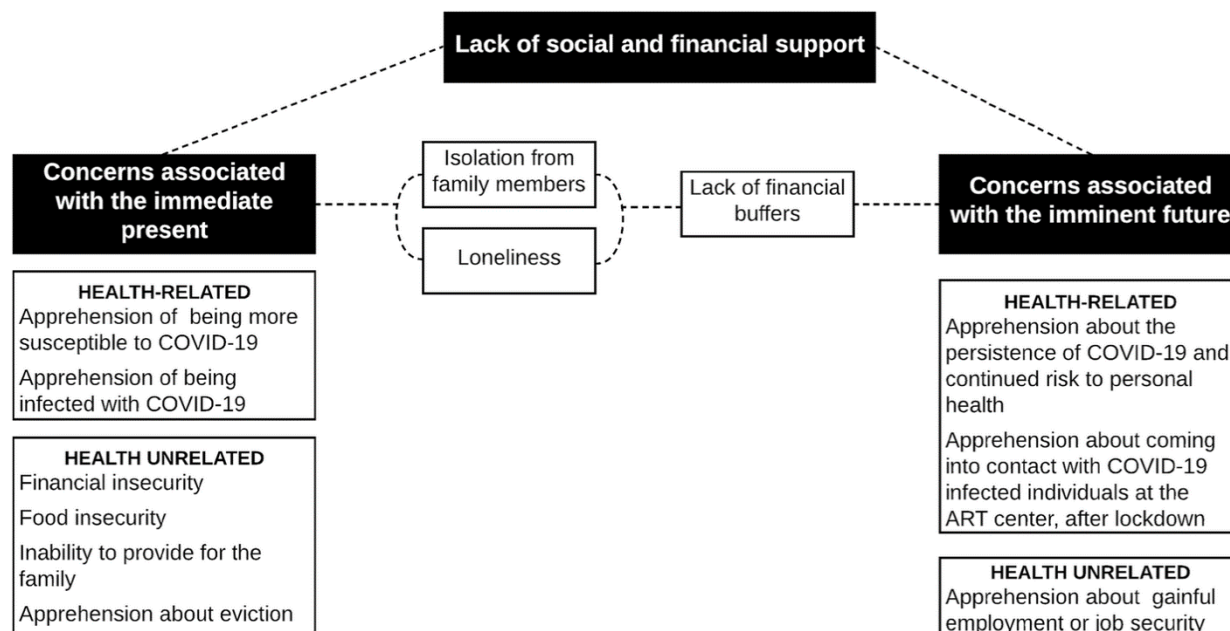
The Joint United Nations Program, followed by the Government of India, has set-up 90-90-90 targets for HIV/AIDS wherein 90% who are positive know their status, 90% who know their status are on treatments and 90% who are on treatment experience effective viral load suppression. With an intense review of literature and on-ground experience, Lazarus et al., felt an urgent need to improve the health-related Quality of life by fighting the challenges including mental health, non-communicable diseases, HIV related social stigma, discrimination, socio-demographic factors.

Figure 2.18 – The proposed Lazarus et al., fourth 90 target to UNAIDS 90-90-90 targets[99]
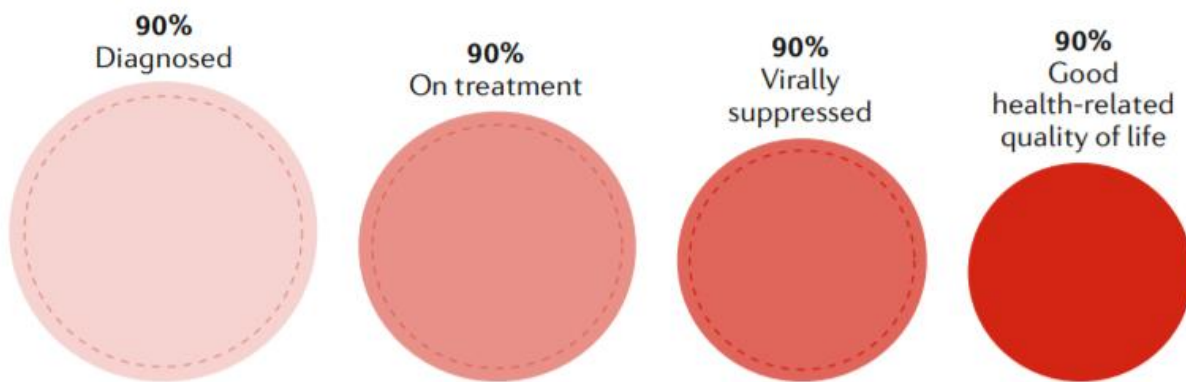
Lazarus et al., proposed a fourth 90 (90% of successfully treated PLHA to be achieving good health related QoL) (Figure 2.18). Our study also focused on most of these factors to assess the nutritional status of PLHA and various factors contributing to it through prospective approach with an aim to improve the Quality of life and reduce morbidity and mortality among PLHA in the long run.

2.18 NEED FOR THE STUDY

The available literature on the prevalence and socio-economic factors associated with malnutrition among PLHA in India is limited, and not well documented. The proper, as well as a feasible implementation of nutritional support for the PLHA and its integration with the routine ART

package requires a clear understanding on the factors associated with malnutrition. Our study focuses on the following aspects -

(1)   Nutritional status by studying whether food and nutrition assistance being presently given to PLHA or not.

(2)   Our research aimed to study the association of socio-economic and cultural factors on nutritional status of PLHA's. This study specifically focused on food insecurity, job security, stigma, food consumption and cooking practices, and WaSH (Water, Sanitation and Hygiene) practices that could potentially influence the nutritional status of PLHA and malnutrition is measured by their BMI, Haemoglobin level (Hb%), serum albumin and total protein levels.

(3)   Literature from the western world suggests an increase in the prevalence of overweight and obesity among PLHA (99,100). However similar data among PLHA is lacking from the Indian sub-continent. Our study attempts to estimate the prevalence of overweight and, or obesity among PLHA in India. This becomes relevant with the latest WHO guidelines that led to test and start the ART immediately on the diagnosis. Data from recent studies indicate that early initiation of ART enhances recovery of CD4 counts at a much faster rate, thereby enhancing the rate of recovery, and further reducing the incidence of opportunistic infections. This puts the patient on the path of nutritional recovery, and with further improvement, chances of over-weight and obesity if calories and the quality of food are not kept under watch.

(4)   Finally, we envisage that the information that emerges from this study with regards to factors influencing the nutritional status of PLHA in India will bring out some objective evidence, that may help in framing policy for nutritional care to PLHA.

AIM AND OBJECTIVES

3.1 AIM.

To assess the nutritional status of ART-Naïve PLHA and their socio-demographic factors by prospectively following them for one year.

3.2 OBJECTIVES OF THE STUDY.

(i) To assess the nutritional status of PLHA's who were started on ART for the first time (ART-naive patients) by following them up over a period of one year.

(ii) To know the socio-demographic profile of PLHA's and their association with nutritional status at the end of one year of follow-up.

(iii) To assess the presence of selected risk factors associated with non-communicable diseases among the study participants.

(iv) To propose suitable recommendations to the policymakers.

3.3 HYPOTHESIS

The nutritional status of PLHA on ART is influenced by socio-demographic factors such as job insecurity, food insecurity, QoL and WaSH practices, either directly or indirectly as a result of the individual's HIV status. Further, enhanced immune reconstitution as a result of betterment in ART, with negligence in the quality of diet in PLHA has led in the resultant rise in overweight and obese individuals.

MATERIALS AND METHODS

4.1 *Study design and participants*

Prospective study wherein PLHA who were started on ART for the first time (ART-naive patients) were enrolled and followed up for one year from their inclusion date in the study. Baseline socio-demographic details were documented, and their nutritional status followed up throughout study duration.

4.2 *Study Place*

The study was carried out in the Pune district, Maharashtra, which is one of the highest prevalence regions for HIV. ART-naive patients who were registered in all the five Institutional ART centers in Pune were included in the study.

4.3 *Study Duration*

3 years (planning stage to analysis, Oct 2015 to Oct 2018).

4.4 *Inclusion criteria*

- HIV positive adult patients who have been initiated on ART for the first time and who have consented to participate in the study.

- HIV positive patients who are permanent residents of the catchment area of respective ART centre or are available in the study area for at least one year of follow-up.

4.5 Exclusion criteria

- HIV patients with opportunistic infections, especially gastrointestinal infections at the time of enrollment.

- PLHA with HIV wasting syndrome.

- PLHA with chronic debilitating diseases like malignancy, diabetes mellitus and thyroid

disease etc.

- Pregnant females.

- Migratory/nomadic HIV positive patients.

4.6 Sample size calculation

The sample size for the study was worked out to be 430 by using the following formula:

$$n = z_{(1-\alpha/2)}^2 \, pq \, /d^2$$

where, $z_{(1-\alpha/2)}$ is Z score at $\alpha = 5\%$ and 95% CI,

Taking into consideration the risk of developing malnutrition as per a recent study[19] as 55% and "d", the acceptable error of difference between the study results and the true value of 5 %, with a 15% loss-to-follow-up, the sample size was estimated to be **430.**

4.7 Ethical clearance

Ethical clearance was obtained from the Institutional Ethical Clearance Committee of Shri. B. M. Patil Medical College, BLDE University (IEC Ref No-95/2014-15 dated 15 Nov 2014). Approval from National AIDS Control Organisation (NACO), Maharashtra State AIDS control society (MSACS) was also obtained, before the start of the study. Finally, permission from all the institutions where ART centres were located was also obtained, before enrolling the patients in the study. All patients were recruited for the study on a voluntary basis, confidentiality was ensured in every step and were explained about the research in the local language, and informed consent was obtained during each interview, blood sampling and retrieval of records.

4.8 Data collection

Subjects satisfying the inclusion and exclusion criteria were selected from all the five ART centers after explaining the scope and nature of the study and taking informed consent. Strict confidentiality was ensured during the entire process. Systematic random sampling was employed to achieve the target sample size from all five ART centers.

Anthropometric measurements (height and weight) were carried out for all the subjects following recommended measurement protocols laid down by the International Standards of Anthropometric Assessments (ISAQ), and laboratory investigations were carried out as per the NACO protocol.

4.9 *Study instrument*

Data was collected by using a pre-tested, semi-structured, interviewer-administered questionnaire at baseline time-point (initiation of ART), after six months and at the end of one year. The questionnaire comprised of the following domains and variables asked and measured (including blood sampling for lab parameters) (Figure 4.9):

- Socio-demographic characteristics: Age, sex, religion, caste, marital status, family type and size, education, income, residence, employment status.

- Associated morbidities/treatment status/hospital admission status/drug side effects

- Dietary assessment, cooking and food consumption practices, WaSH practices.

- Quality of Life (QoL), Household Food Insecurity Access Scale (HFIAS), Perceived Health Status Scale.

- Anthropometry was measured by using stadiometer for height, and a weighing machine for weight, measuring tape for hip circumference as per the ISAK Standards. Body Mass Index (BMI) was calculated by using standard formula of weight (Kgs) by height in meters square (m2) and expressed in Kgs/m2.

Participants' nutritional status were classified into underweight, normal and overweight categories as per the WHO Asians classification of BMI.

- Selective NCD risk factors from WHO Steps instrument[102] was included in study protocol. Yoga practice and physical activity among PLHA was also asked

- Biochemical measurements [CD4, Serum albumin, total protein, Hb%, total cholesterol, blood sugar, serum creatinine and serum bilirubin] as per NACO standards

Table 4.9 - Data Collection Time matrix and and variables measured at each point during the follow-up

OCT 15 - FEB 2016 Baseline Data	APR 16 - JUL 2016 Sixth monthly Data	OCT 16 – FEB 2017 After one-year Data
Socio-demographic profile *Clinical data-* *Anthropometric data* *NCD risk factors profile* *Investigations* Hb%, Sr. Albumin, Total Protein Blood sugar (Random) Total Cholesterol Blood Urea, Sr creatinine Serum Bilirubin	*Socio-demographic profile* *(Any changes being noted)* *Clinical data* *Anthropometric data* *Diet*	*Socio-demographic profile* *Clinical data in detail* *Anthropometric data* *NCD risk factors profile* *Investigations* *Hygiene and sanitation aspects* *Household food insecurity access scale (HFIAS)* *Diet* *WHOQOL (partial)*

4.10 *Data analysis*

Data entry was done in an Excel sheet. The data was checked for adequacy and completeness. The responses were coded either using standard classifications or by using the median cut-off. Analysis was done using SPSS software (version 20.0). Dietary assessment was made based on the weekly/monthly consumption of milk, eggs, fruits, green leafy vegetables and monthly intake of

chicken, fish. The data was categorised utilizing the scoring system into adequate (Equal to or > 50% scores) and inadequate diet (< 50% scores). Quality of life was assessed by the World Health Organisation (WHO) Quality of Life (QoL) - HIV brief questionnaire[102] and were categorized into Poor QOL (with less than 60% QOL score), Good QOL (with 60-79% QOL score) and Excellent QOL (with equal to or more than 80% QOL score). Household food insecurity was assessed utilizing the Household Food Insecurity Access Scale (HFIAS) [103], which consists of a set of nine questions, and participants were classified as food secure and food insecure using standard scoring system as mentioned in HFIAS protocol[103]. Perceived health status of the participants before and after starting ART was assessed by means of EQ 5D 3L visual analogue scale (VAS) [104], wherein best possible health state marked as 10 and worst imaginable health state marked as 0 was used and finally percentage of PLHA with less than five before-after-effect (difference) and more than five before-after-effect (difference) was assessed.

4.11 *Dependent variables*

Underweight / Normal weight / Overweight / Obesity (BMI)/selected biochemical parameters.

4.12 *Independent variables*

Sociodemographic factors, diet, disclosure status, food & Job insecurity, hygiene and sanitation conditions, cooking & eating habits, health status perception.

4.13 *Loss to follow up*

Being a prospective study, with anticipation of loss to follow up, the following measures were taken to minimize loss to follow-up to a bare minimum.

(a) In sample size calculation, 15% extra sample size was taken to cater for 15% loss to follow up if at all it occurs.

(b) As per inclusion criteria, only the patients who were permanent residents of that area in which the ART centre is located were taken into the study and other temporary/migratory patients were excluded from the study.

(c) All due care was taken while including the patients in the study. They were explained about the importance of the study, especially the importance of follow up.

(d) Exact address and mobile number of all the patients along with their local relatives were recorded, and the patients were instructed to intimate long-term change of address or migration, if any.

(e) All the patients registered in the ART centre are supposed to collect the medicines monthly with proper documentation. If a patient fails to collect the medicines, the ART counsellor will call the patient on mobile and visit the patient, motivate him and ask him to resume follow-up. This is, in fact the strength of NACO-established ART centres.

<p style="text-align:center"><u>RESULTS AND DISCUSSION</u></p>

Overall, 430 participants were enrolled in the study, and baseline data were collected from them. However, only 378 remained till the end of the study period (13 months) and were included in the final analysis. At the same time, the remaining 23 participants were lost to follow-up, 22 expired, and 07 transferred out (Figure 5.1.1). Concerning blood investigations, at the baseline, all 430 participants were tested for blood parameters, but only 217 participants could undertake blood investigations at the end of 12 months. The main reasons for the same were lack of time for PLHA for sample collection, and most of them were coming to ART centres after 1200 hrs after finishing their morning work, thereby missing the sample collection period. Some participants did not give consent for blood sampling. So, concerning blood haemoglobin, serum albumin, total protein, only 217 participants samples were used for final analysis.

Figure 5.1.1: Flowchart showing the enrolled and dropped out number of participants with reasons
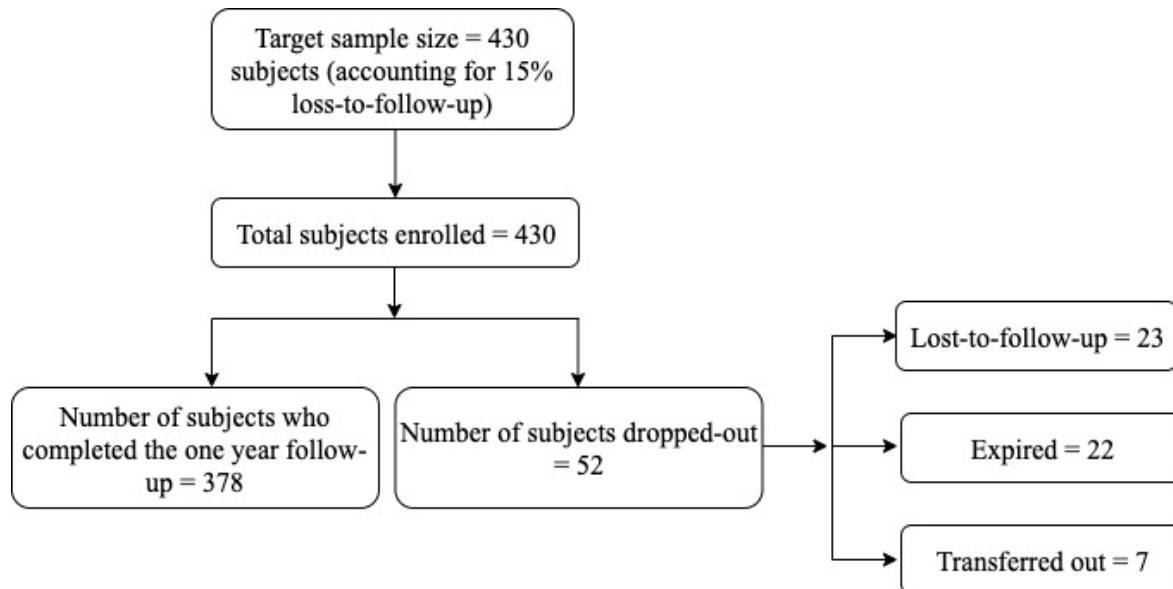
<p style="text-align:center">Table 5.1.1: Socio-demographic profile of study subjects</p>

Socio-demographic variables	Frequency (N = 378)	Percentage
Age category		
18 – 25 years	24	6.3
26 – 35 years	89	23.5
36 – 50 years	193	51.1
50 – 60 years	46	12.2
> 60 years	26	6.9
Education category		
Illiterate	80	21.2
Primary	69	18.3
Secondary	169	44.7
College and above	60	15.9
Individual Income category (Per month, figures in rupees)		
Zero	119	31.5
< 5000	118	31.2
5001 – 10000	98	25.9
10001- 15000	21	5.6
15001- 20000	6	1.6
> 20000	16	4.2
Per capita category (Based on family income, Modified BG prasad Scale - Jan 2018)		
Upper class	36	9.52
Upper middle class	89	23.5
Middle class	116	30.6
Lower middle class	93	24.6
Lower class	44	11.6

Table 5.1.2: Socio-demographic profile of study subjects (Contd….)

Job category		
Heavy (Construction/agriculture)	123	32.5
Salaried	35	9.3
Business	43	11.4
Unemployed	114	30.2
Driver	28	7.4
Others	35	9.3
Family		
Joint	102	27.0
Nuclear	276	73.0
Religion		
Hindu	363	96.0
Muslim	15	4.0
Marital status		
Married	249	65.9
Separated	20	5.3
Single	27	7.1
Widow	82	21.7

Figure 5.1.2: Sex distribution of study subjects
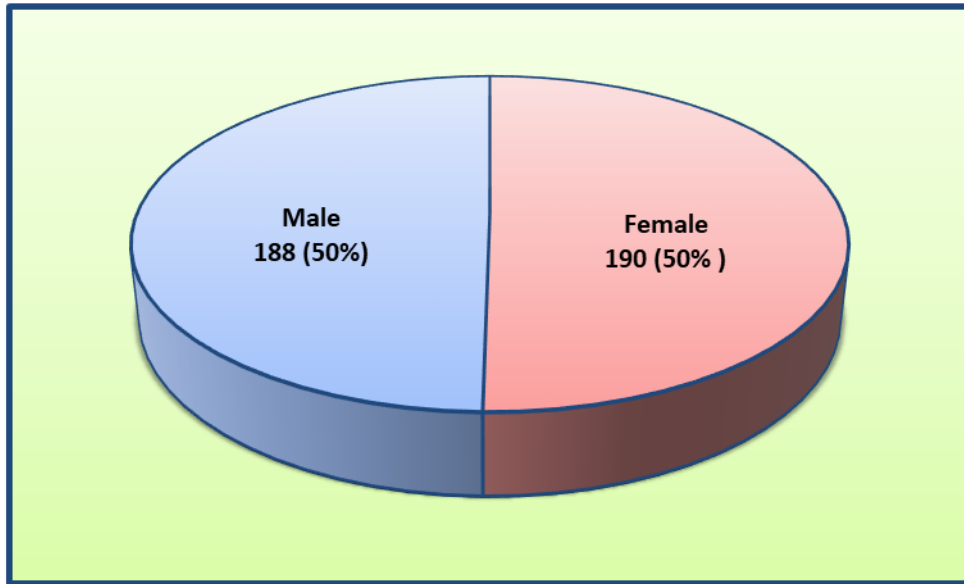
Figure 5.1.3: Urban/rural distribution of study subjects
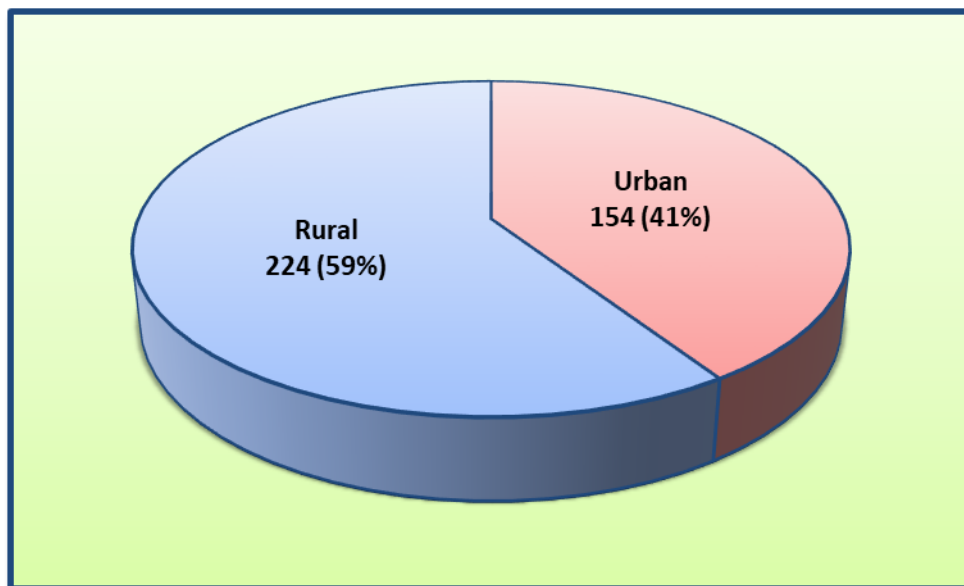
Figure 5.1.4: Ration card holding distribution of study subjects
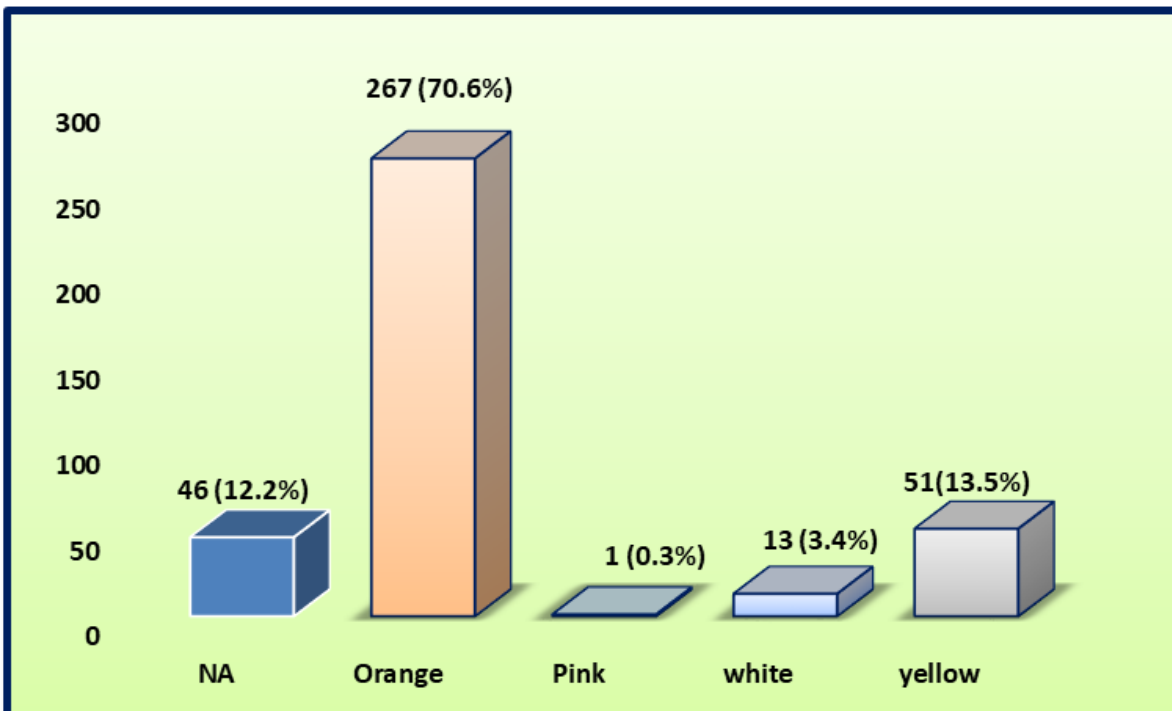
Yellow Ration card – For families below poverty line (BPL category, yearly income less than 15,000)

Orange Ration card – For families with yearly income between 15,000 to less than 1 lakh

White Ration card – For families with yearly income of 1 lakh and above

Pink Ration card – For families of above poverty line with special subsidies under various state schemes

NA – Not available

Figure 5.1.5: Ration card Utilization distribution of study subjects
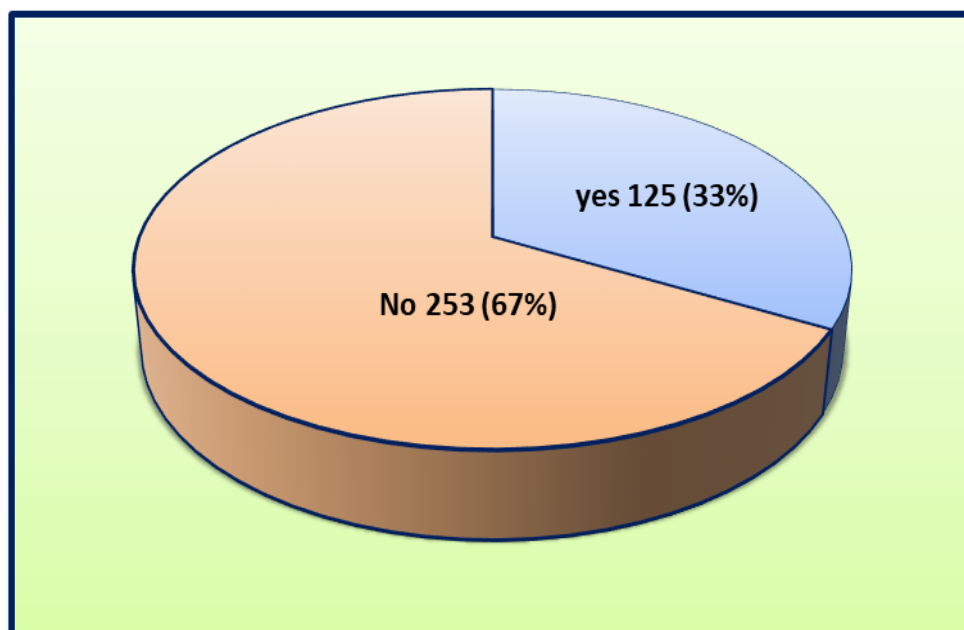
5.1 *Baseline demographic characteristics of participants (n=378)*

Our study sample predominantly constituted PLHA coming mainly from rural areas (59%) (Figure 23) and 49% were Men (Figure 5.1.3). The mean age of the study participants was around 42 years. About 21% were illiterate, and out of the remaining, 45% were educated up to secondary school (10th Grade) (Table 5.1.1). 31.5% of the subjects were unemployed/ had no regular income source, while 31% had a monthly payment of less than 5000 INR. As per the modified B.G. Prasad scale of socio-economic status (as per Consumer price index Jan 2018) [105], the majority (31%) of the participants belonged to the middle class, while 12% were in the lower class. About 32% of them were employed at a job demanding heavy work (construction/ agriculture) (Table 5.1.2). 66 % were married, 22% were widowed, 73% of them had nuclear families. HIV status was not disclosed to the family members by 10 % of PLHA and 0.8% had not disclosed their HIV status to even their spouse/intimate partner. The majority (98%) of them had not disclosed their HIV status at their workplace mainly because of fear of losing their job, fear of exposure of seropositive status to other members, isolation from workplace and society. Non-disclosure of their status at

their the workplace also affects frequent requirement of leave for care, support, treatment, thereby PLHA may lose job since authorities are unaware of disease profile which would further affect their nutritional status.

Concerning type of the ration card possessed, 71% had orange cards (families with yearly income between 15,000 to less than 1 lakh), and 14% had yellow ration cards (Below Poverty Line (BPL) category, families with annual income less than 15,000) (Figure 5.1.4). Only 33% utilized their ration card for collecting monthly rations (Figure 5.1.4). The main reasons for the low/non-utilization of ration card were the timings at which the ration shops opened which were inconvenient for working PLHA to visit them. Some had shifted to the city for work, being migrants, so could not go back to their villages to collect monthly ration, at times stock unavailability at the ration shops, poor quality of the ration given (rice, pulses, palm oil), and limited quantity were other reasons. It was also seen among unemployed PLHA, the majority couldn't use the ration card as they were migrated to a different place and could not change or update the ration card details.

Table 5.1.3: Disclosure status of study subjects

Disclosure status	Frequency (N = 378)	Percentage
Disclosure at home		
Not applicable	1	0.3
No	38	10.1
Yes	339	89.7
Disclosure to Spouse		
Not applicable	131	34.7
No	3	0.8
Yes	244	64.6
Disclosure to others		
No	377	99.7
Yes	1	0.3

Table 5.1.4: Clinical profile of study participants with selected variables

Clinical profile variables	Frequency (N = 378)	Percentage
ART initiation		
At the time of detection	347	91.8
< 2 years of detection	4	1.1
2- 5 years of detection	16	4.2
> 5 years of detection	11	2.9
CD4 baseline category		
Less than 100	74	19.6
100 – 350	227	60.1
350 – 500	51	13.5
500	26	6.9
CD4 increase category		
No increase	232	61.4
Increase upto 500	85	22.5
Increase upto 500 and double the base CD4	61	16.1
Spouse status		
Not applicable	134	35.4
Negative - spouse	116	30.7
Positive - spouse	128	33.9
Children Status		
Not applicable*/ Negative	368	97.4
Positive (On ART)	10	2.6
* includes participants who are unmarried or with no children		

Figure 5.1.6: ART side-effects* distribution of study subjects
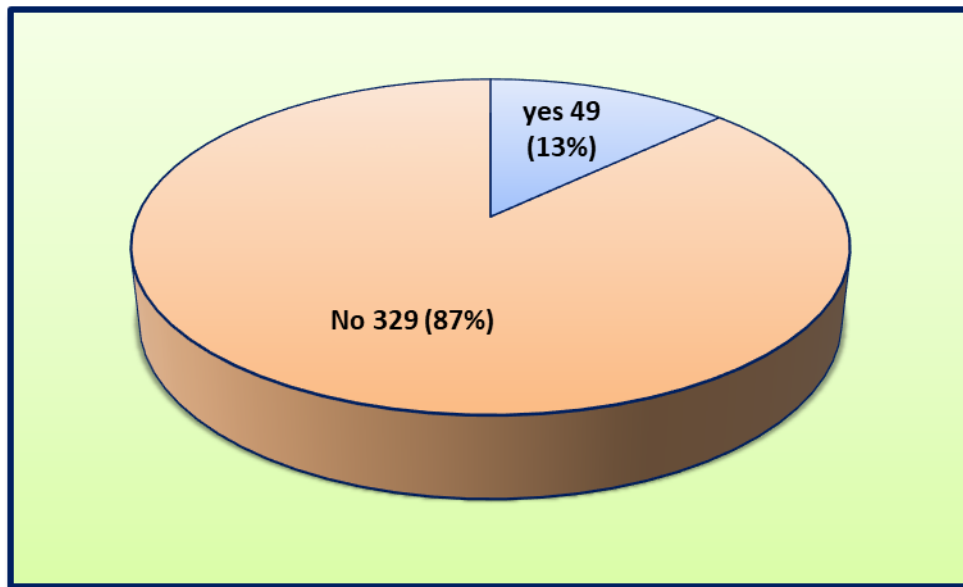
*Side effects category - Anaemia, gastritis, rash, weakness, vomiting

Figure 5.1.7: Study participants' distribution as per their opportunistic infections (OI)**
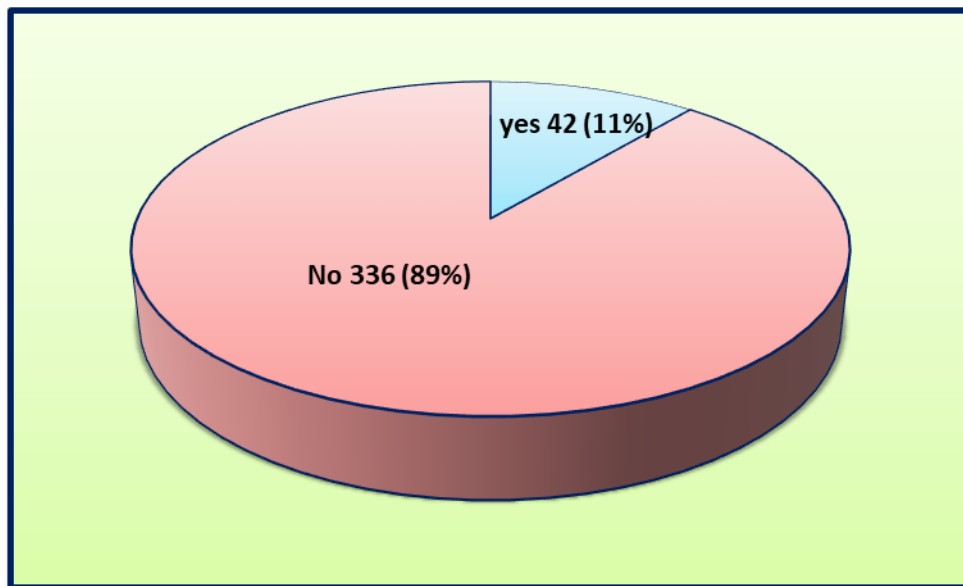
** Taenias, Vaginal Candidaisis, TB, Herpes, Meningitis, Cardiac problem

5.2 *Clinical profile of participants*

The majority, 92% initiated ART at the time of detection and 60% of the subjects-initiated ART at CD4 counts between 100 to 350 cells/cu.mm. About 20% of the subjects had CD4 counts less than 100 at the time of initiation of ART. The majority (61%) had no increase in the CD4 count in spite of one year of ART, while 23% showed a rise of up to 500cells/cu.mm, with 16 % showing a CD4 count above 500 cells/cu.mm, almost doubling from the baseline count (Table 5.1.4). During the study, 2015 NACO guidelines were followed for the initiation of ART by the ART centres, wherein ART was started for those with CD4 count of 500.

Spouse was also positive for HIV status in 34% of the subjects, and 3% had children who were HIV positive and on ART. No significant side-effects were reported in 87% of the subjects, while 13% had side-effects such as anaemia, gastritis, skin rash, weakness and vomiting (Figure 5.1.6). Opportunistic infections, one or the other, were reported in 11% of the subjects such as Taeniasis, vaginal candidiasis, tuberculosis, herpes infections, cryptococcal meningitis (Figure 5.1.7).

5.3.1 *Objective 1 - Nutritional status of the study participants measured in terms of BMI (followed-up over the one-year period)*

Table 5.3.1.1: Baseline and after one-year Nutritional status of study subjects

	Frequency (N = 378)	Percentage	Frequency (N = 378)	Percentage
	Baseline		**One year after**	
BMI Category (Asians classification)				
Underweight (BMI <18.5)	155	41.0	132	34.9
Normal (BMI 18.5 – 22.9)	123	32.5	127	33.6
At risk (Overweight), BMI 23 – 24.9	43	11.4	53	14.0
Obese (BMI >25)	57	15.1	66	17.5
Blood parameters				
Anaemia	160	73.7	130	59.9
Low Albumin	37	17.1	28	12.9
Low total protein	38	17.5	30	13.8

Table 5.3.1.2: Status of Dietary intake of study subjects

Dietary intake	**Frequency (N = 378)**	**Percentage**
Inadequate	272	72.0
Adequate	106	28.0
Total	378	100.0

About 41% of PLHA were underweight (BMI <18.5) at the baseline anthropometric assessment. Despite one year of cost-free ART and an adherence rate of 90%, the estimated prevalence of undernutrition was 35% at the end of one year (Table 5.3.1.1). Anaemia was seen in 74% of the subjects at baseline, and at the end of one year, 60% continued to remain anaemic. Low albumin was seen in 17% of the subjects at a baseline measurement, and 13% continued to show low levels

even after one year. Low total protein was seen in 18% and 14% of the subjects at baseline and after 1-year assessments, respectively (Table 5.3.1.1). Based on the dietary recall, the amount of fruits, milk, green leafy vegetables, eggs, chicken/meat and fish intake per week was used to calculate the dietary score. The inadequate dietary score was documented for 72% of PLHA (Table 5.3.1.2).

Ideally, because of cost-free ART, adherence rate of 90%, lesser incidence of side effects and opportunistic infections, all nutritional parameters, including BMI, Hb%, total protein and albumin should have been increased. Factors that have led to abnormal nutritional parameters are discussed below and need to be addressed on priority.

5.3.2 *Discussion*

Even after one year of treatment, undernutrition in our study was at 35%, anaemia at 60%, low albumin at 13%, low total protein at 14%, which were higher despite regular treatment and monitoring. Most important factors being low consumption of fruits, milk, green leafy vegetables, eggs, chicken/meat and fish per week, as evident by 72% having inadequate dietary score coupled with zero/low incomes status (< 5000 per month) of 63% of PLHA, unemployment (30%) and doing heavy constriction/agriculture work (33%) (Table 5.1.2). This was also coupled with almost all HIV status nondisclosure rate at the workplace (Table 5.1.3), which affected their frequent requirement of leave for care, support, treatment leading to mental stress, indirectly affecting nutritional status. Only 33% used a ration card for subsidized ration while the rest (Majority) (Figure 5.1.5) did not have any food assistance facility being provided nor utilized. Our findings correlate with cross-sectional studies carried out in India by *Anand et al.,*[104] and *Sachdeva et al.,* [6], in Ethiopia by *Hadgu et al.,* [24] and Daka DW et al., [107], in Senegalby Benzekri NA et al., [108] showing increased prevalence of undernutrition while in Nepal by Thapa *et al.,*[35] and

Khatri S *et al.,* [109] showed in independent studies, the prevalence of undernutrition below 20% (Table 5.3.2).

Table 5.3.2 : Undernutrition status among PLHA as per various studies across the world

Author	Year/Place	Study type	Nutritional status	Sample size
Anand et al	2012/ India	cross-sectional	40% Undernutrition mean BMI =19.73±3.55 kg/m2	400
Sachdeva et al	2014/ North India	cross-sectional	mean weight = 58.6±11.7 kg and BMI = 21.5±3.7 kg/m2	100
Thapa et al.	2015/ Nepal	cross-sectional	19.93% Undernutrition	180
Khatri S et al	2020/ Nepal	cross-sectional	18.3% Undernutrition	350
Hadgu et al.	2012/Ethiopia	cross-sectional	42.3% Undernutrition (of which 12% were severely undernourished)	276 women
Benzekri NA	2018/Senegal	Retrospective	37% Undernutrition	1471
Sicotte M	2015/West Africa	Prospective study	36 % undernutrition – Group I 31 % undernutrition – Group II	250 and 372

The review of the literature did not show any recent Indian prospective study correlating nutritional status, and ART in PLHA. In our prospective study, the baseline undernutrition status was 41%. After one year it was 34.9% while study carried out by Benzekri NA et al., [108] in Senegal on 1471 participants, the prevalence of undernutrition decreased from 52% to 37% over six years and major predictors of a still high prevalence of undernutrition even after six years of ART were lesser CD4 count and WHO stage 3 and 4 while education and ART were protective. The authors also highlighted the need of nutritional interventions explicitly targeted to men and women to effectively control undernutrition.

Sicotte M *et al.,* [110] also showed a very high prevalence of undernutrition of 36 % in Group I and 31 % in Group II. According to the authors, there were initial early gains in BMI. Still, malnutrition persisted in both groups despite ART for one year and emphasized that on HAART may not be enough and there is a need to improve nutritional and food insecurity aspects. In this study of Sicotte M *et al.,* [110], low Hb%, low albumin and low CD4 count were associated with Low BMI. Low albumin was found in 22 % of study participants while low Hb% was found in 58% at baseline and after three months there was an improvement. However, improvement stopped and plateaued after one year, while in our study, low albumin and low Hb% were 74% and 17% at baseline and after one year also it was still high at 60% and 13% respectively. Inadequate dietary intake and high undernutrition status even after one year along with other factors contributed to low Hb% and low Albumin even after one year of ART. High prevalence of anaemia was also found in various studies carried outside India by Ageru TA *et al.,*(35%)[111], Gebremedhin KB *et al.,*(35%)[112] and Aynalem YA *et al.,*(26%)[113]. These studies showed that, along with nutritional status there are various other factors responsible for low Hb% status, such as opportunistic infections, WHO clinical stage, parasitic intestinal infections and duration of HIV status.

In our study, only 33% of PLHA were consuming vegetables and 18% were consuming fruits at least thrice weekly. The mean weight, mean BMI and dietary inadequacy of study subjects after one year of ART were 54.84 Kgs, 21.12 Kgs/m^2 and 72%. Similarly, in a study carried out by Sachdeva *et al.,* [6] showed mean weight and mean BMI of study participants as 58.6Kg and 21.5, respectively and had energy intake significantly lower than recommended daily intake. Findings were also similar in the study carried out by Isabirye N *et al.,* [114] wherein diet consumed by study subjects were much lower than recommended for most nutrients and deficiency was more among women than men. Hadgu *et al.,*[106] also showed that inadequate dietary diversity was an

independent predictor associated with undernutrition, with 53% having inadequate dietary diversity.

Anand *et al.,* [104] also showed that the majority of participants could not meet the dietary requirement of majority of micronutrients laid down by ICMR and their Nutrient Adequacy Ratio (NAR) was low for majority of nutrients. Similarly, in a study carried out by Khatri *et al*[109] in Nepal, dietary diversity was low in 62% of participants.

In majority of the above studies, the major predictors of undernutrition even after initiation of ART were less CD4 counts, clinical stage 3 and 4 and associated opportunistic infections, and low dietary adequacy and diversity. While in our study, despite continuous ART with an adherence rate of more than 95% and monthly follow-up, with no significant opportunistic infections, there was no significant improvement of undernutrition, and undernutrition persisted in 35% of the participants. This indicates that dietary inadequacy and various factors contributing to dietary inadequacy such as job insecurity, food insecurity, Quality of life, perceived health status, cooking and food consumption, eating practices, WaSH practices etc played an important role. All these factors have been discussed in the succeeding paragraphs.

5.4.1 *Objective 2*

   Socio-demographic profile of PLHA changes over a period of 1 year in study participants

This objective was assessed explicitly by using the following components: Quality of life (QOL), food insecurity, state of health, job insecurity, income insecurity, diet adequacy, WaSH practices, cooking and eating habits.

5.4.2 *Quality of Life (QOL)*

WHO defined QOL as individual's perceptions of their position in life in the context of the culture and value systems in which they live and concerning their goals, expectations, standards and concerns[115].

With the advent of HAART, the course of HIV infection has been changed from deadly disease to chronically manageable disease. At the same time, it has helped us to shift focus from fighting virus to improving the QOL of PLHA. While QOL is an indirect indicator of nutritional status, an excellent QOL helps the PLHA to overcome the disease progression and maintain a healthy status for a long time and help in assessing the effectiveness of treatment. So, assessment of QOL among PLHA becomes highly important so that factors affecting them can be identified and actions are taken appropriately. QOL in our study was assessed by using the WHO QOL Brief, which showed that the majority, 57%, had a poor QOL index, while 32% and 12% had good and excellent QOL indices, respectively (Table 5.4.2).

Table 5.4.2: Quality of life (QOL) Status of study subjects

QOL	Frequency (N = 378)	Percentage	95 % CI	
Excellent	43	11.4	8.4%	15.1%
Good	119	31.5	26.9%	36.5%
Poor	216	57.1	52.0%	62.2%
Total	378	100.0		

Similarly, Anand D *et al*.,[79] carried out a study in eastern India concerning QOL profile of subjects, indicated a moderate score in all domains of QOL with overall poor QOL while another study by Anuradha S *et al.,*[82] in Delhi showed QOL in terms of mean physical health summary (PHS) score and mental health summary (MHS) score as 48.042 ± 8.27 and 52.43 ± 8.79 respectively, with 0 as the worst health state possible and 100 as the best health state possible, indicating moderate QOL, among majority participants. Among the domains scores, QOL, health transition scores and general health perception scores were poorer when compared to others.

Kohli RM *et al.,*[116] in Pune also showed QOL scores were significantly lower among the study participants, especially among women despite having slow progressive disease, and emphasized the need for women psycho-social interventions. One more study carried out among HIV positive slum dwellers in Mumbai by Gupta SK et al.,[117] showed that the mean score of overall QOL was below average (10.95) on a scale of 4 to 20, and the general health score was also below average on a scale of 5 to 25.

On the contrary, Sarkar T *et al.,*[118] at the centre of excellence in HIV care at Tropical medicine school, Kolkatta, with better services being provided, showed good QOL among study participants

in terms of environmental, physical as well as the psychological domain in the Indian setting. Even in a cross-sectional study carried out at Ghanaby Osei-Yeboah J *et al*.,[78] 80% and 9% presented with excellent and good overall QOL, respectively, whilst only 11% had their life affected negatively by HIV/AIDS with overall QOL while in Psychological component the scores were 21% (Excellent), 66% (Good) and 3% (poor). Discussion on the association of QOL and nutritional status has been carried out in succeeding sections.

5.4.3 *Food insecurity*

As per USAID, Food security has been defined as a state in which "all people at all times have both physical and economic access to sufficient food to meet their dietary needs for a productive and healthy life". Ideally, food security comprises three distinct variables, which include food availability, food access and food utilization. It also depends on food storage, hygiene and sanitation aspects, good awareness of nutrition and childcare techniques. Food insecurity using a complex pathway, leads to both forms of malnutrition (undernutrition and overweight/obesity) (Figure 5.4.3) (119). Similarly, various factors like nutritional status, psychological aspects, behavioural changes, including risky sexual behaviour and poor ART adherence, interlink HIV/AIDS and Food insecurity through a vicious cycle with one affecting each other and vice versa[120]. So, assessment of food insecurity among PLHA becomes highly important with emphasis on undernutrition.

Figure 5.4.3 : Pathways from Food insecurity to multiple forms of malnutrition (119)
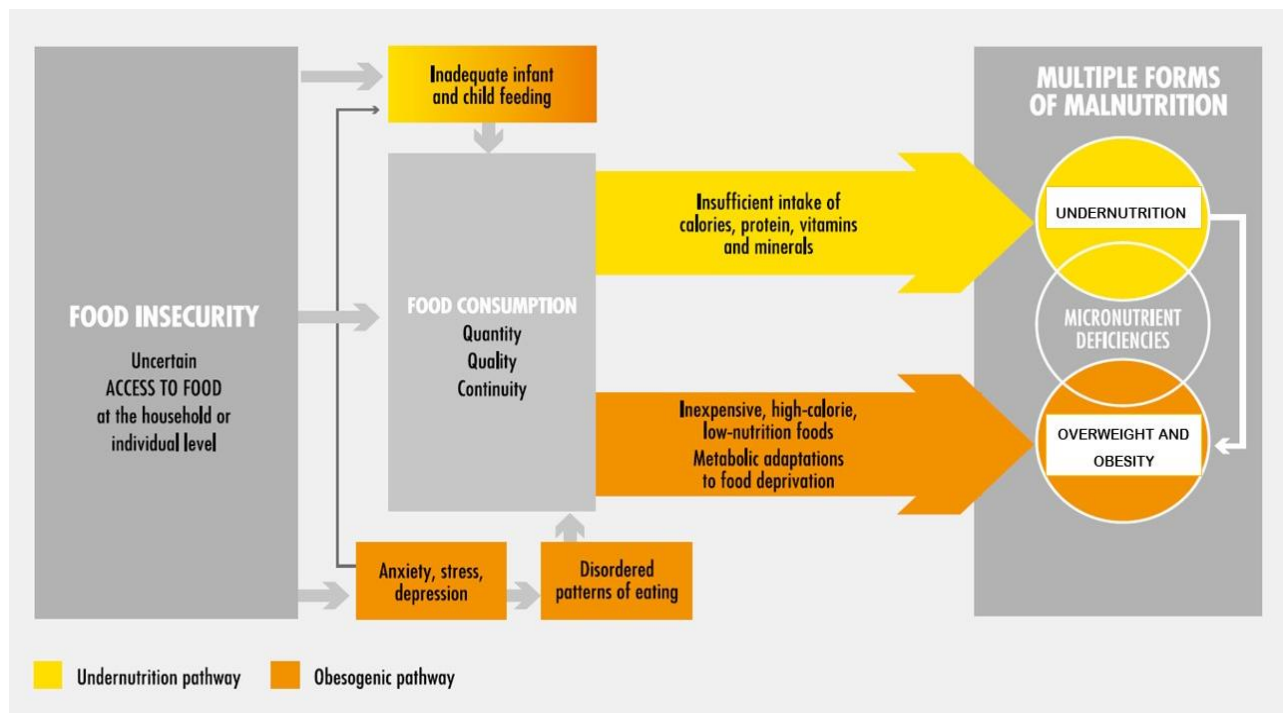
In our study, we assessed food insecurity at the end of one year of follow up, using the Household Food Insecurity Access Scale (HFIAS)[103] (attached in annexures), which consists of a set of nine questions, and participants were classified as food secure and food insecure using standard scoring system as mentioned in HFIAS protocol[103]. In our study, majority (53%) showed food insecurity (Table 5.4.3.1) which is in line with various studies carried out across the world with food insecurity in the range of 29% to 71% among PLHA (Table 5.4.3.2). Even in developed countries like the USA[62], Australia[63] and Canada[64], studies have shown a significant percentage of food insecurity among PLHA, highlighting the need for food, Cash incentives and socio-economic interventions to overcome food insecurity and improve the quality and health status of PLHA[62-64].

Table 5.4.3.1: Household Food Insecurity Status of study subjects as per HFIAS

HFIAS	Frequency (N = 378)	Percentage
Insecure	200	53
Secure	178	47
Total	378	100

Table 5.4.3.2 : Status of food insecurity among PLHA as per various studies across the world

Author	Year/Place	Study	Food insecure	Sample size
Heylen E et al., (121)	2014/South India	Longitudinal (two years)	45 % (19% men and 26% women)	243 male and 129 females
Weiser SD et al., (122)	2014/ Rural Uganda	Longitudinal (22 months)	40%	284
Tesfaye M et al., (77)	2015/ Ethiopia	cross-sectional	38.87%	348
Normen L et al., (65)	2016/Canada	cross-sectional	5 times more than normal people	1213
Golovaty et al., (62)	2020/United states	cross-sectional	29%	2627
Langton A et al., (64)	2018/Australia	cross-sectional	47%	162
Sholeye O et al., (123)	2017/Nigeria	cross-sectional	71.7%	244

5.4.4 *Perceived Health status*

One of the impacts of HAART is that it improves the health status of PLHA which in turn improves

the Quality of Life. In our study we tried to assess the perceived health status at the baseline during

the start of ART and then after one year of ART to see the changes in perceived health status by PLHA by use of EQ 5D 3L visual analogue scale (VAS) [103] (Figure 5.4.4) with 0 as worst health and 100 as best health one can imagine. The aftereffect was categorized into less-than–or-equal-to five before-after-effect (difference) and more than five before-after-effect (difference). The majority (62%) had aftereffect health status classified as less than or equal to five, indicating no significant improvement in health status than the baseline (Table 5.4.4). Our results was in contrary with findings from Lifson A *et al.,* to self-assess the overall health status of PLHA on ART using VAS and found out that the mean VAS score was 80.9+_15.7, which was lowest for vitality and mental health and highest for physical functioning indicating the HAART do not negatively affect the health status. However, this assessment was made at the start of the antiretroviral naïve trial at baseline with PLHA with CD4 count more than 500. The study's findings were contrary to our study, probably because, in Lifson A et al., study participants with CD4 count greater than 500 were included who had better-perceived health status because of less viral load and lesser opportunistic infections (OIs). On the contrary, OIs increase when CD4 drops to less than 200, leading to deteriorating health status.

Our study findings were also contrary with another study by Jelsma J *et al.,* [124] who used EQ-5D VAS at baseline, one, six and 12 months. The mean score of health status significantly increased from mean of 61.7 (SD+_ 22.7) at baseline and 76.1(SD +_18.5) at 12 months. Our findings of (62%) majority not having significant improvement in health status even after one year of ART probably correlates with the high food insecurity level (53%), poor QOL (57%) and a high percentage of dietary inadequacy (72%) with 35% of undernutrition level seen even after one year of ART which are determinants of health status. Our study findings are also in line with study

carried out by Grosskurth H *et .al.,* [125] in Uganda wherein participants mean VAS score for symptomatic HIV infection was 0.55 (0.62 – 0.69), for minor AIDS-defining illness it was 0.39 (0.37 – 0.42) and for major AIDS-defining illness, was 0.15 (0.13 – 0.17) with 1.00 score used as the best perceived health score.

Figure 5.4.4: Visual analog scale used to assess before and after perceived health status
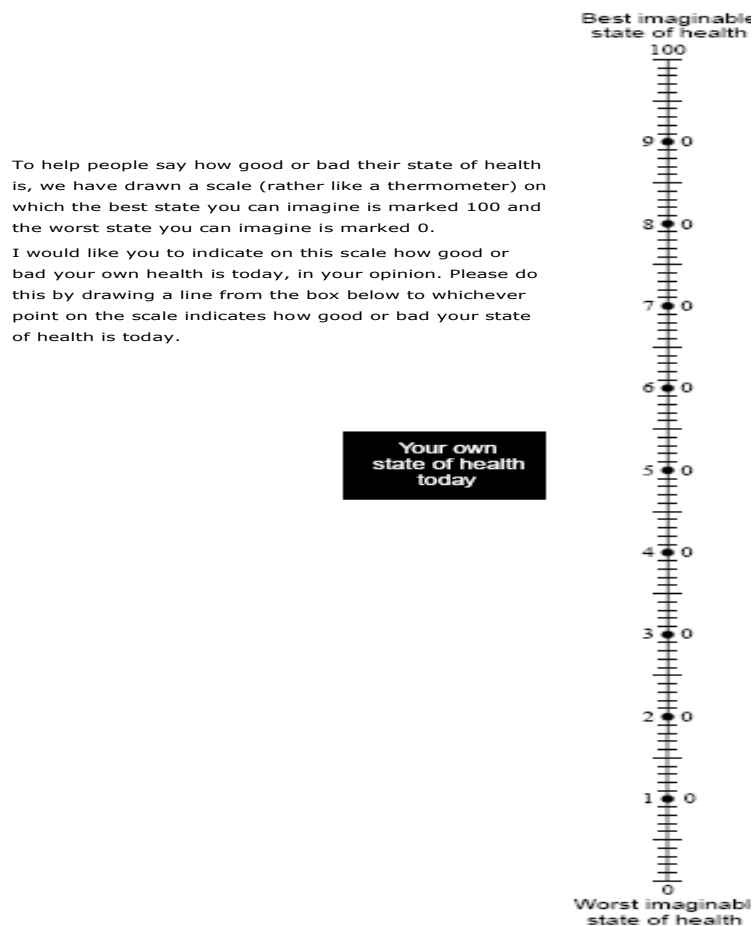
Table 5.4.4: Before and after effect of perceived Health status of study subjects as per

Visual Analog scale

Before - after effect (Difference)	Frequency (N = 378)	Percentage	95 % CI	
Less than or equal to 5	234	61.9	56.8%	66.8%
More than 5	144	38.1	33.2%	43.2%
Total	378	100.0		

5.4.5 *Association of Nutritional status and socio-demographic predictors*

Table 5.4.5.1: Logistic regression of Nutritional status and socio-demographic predictors of study subjects over the period of one year

Variables	No. of respondents (n)	All respondents (N=378)						Female respondents (n=190)			Male respondents (n=188)		
		Univariate logistic regression			Multiple logistic regression			Multiple logistic regression			Multiple logistic regression		
		OR	p-value	95% CI	AOR	p-value	95% CI	AOR	p-value	95% CI	AOR	p-value	95% CI
Change in job status after 1 year													
Changed / new / no Job status	51	1.518	0.170	0.837 - 2.752									
Same status	327												
Change in income after 1 year													
Decreased/ no income	159	1.918	0.002	1.268 - 2.901							4.036	<0.0001	1.873 - 8.695
Improved/ same	219												
Significant change in CD4 count after 1 year													
No increase	232	1.427	0.045	0.940 - 2.165									
Increased	146												
QOL after 1 year													
Poor	216	2.688	0.005	1.345 - 5.372	2.238	0.033	1.065 - 4.700	6.040	0.007	1.636 - 22.294			
Good	119	1.260	0.540	0.602 - 2.634	1.139	0.747	0.517 - 2.511	4.429	0.034	1.117 - 17.558			
Excellent (Reference)	43												
Food security after 1 year													
Insecure	178	2.056	0.001	1.363 - 3.099	1.763	0.013	1.125 - 2.762	2.390	0.008	1.255 - 4.550			
Secure	200												
Dietary diversity													
Inadequate diet	272	0.720	0.153	0.459 - 1.130				0.447	0.033	0.213 - 0.938			
Adequate diet	106												

Kolmogorov-Smirnov test was applied to test the normality of quantitative variables wherein only waist circumference, CD4 count after one year, Hb% at baseline and after one year were normally distributed. That's why the Chi-square test of independence was used to test the association between change in BMI after one year and all independent variables like gender, place of residence Urban / Rural, age, change in job status/ income/ CD4 count/ QOL/ food security/ diet/ health score/ Hb% level/ Albumin level and T protein level. Univariate logistic regression was applied to determine predictors of nutrition status i.e. change in BMI after one year. Independent variables which were significant with $p \leq 0.05$ were retained in the multiple logistic regression models.

Table 5.4.5.2: Logistic regression of Nutritional status and socio-demographic predictors of study subjects over the period of one year (Continued..)

Variables	No. of respondents (n)	All respondents (N=378)						Female respondents (n=190)			Male respondents (n=188)		
		Univariate logistic regression			Multiple logistic regression			Multiple logistic regression			Multiple logistic regression		
		OR	p-value	95% CI	AOR	p-value	95% CI	AOR	P value	95% CI	AOR	p-value	95% CI
Health score after 1 year													
≤5 after effect on health scale	234	3.376	<0.0001	2.171 - 5.252	3.280	<0.0001	2.065 - 5.211	3.165	0.001	1.651 - 6.067	3.667	<0.0001	1.835 - 7.326
>5 after effect on health scale	144												
Change in Hb level after 1 year (n=237)													
Detoriated	133	2.690	0.001	1.526 - 4.741									
Improved/ same	84												
Change in Albumin level after 1 year (n=237)													
Detoriated	24	0.855	0.718	0.365 - 2.002									
Improved/ same	193												
Change in T protein level after 1 year (n=237)													
Detoriated	31	1.295	0.507	0.604 - 2.780									
Improved/ same	186												
Gender													
Female	190	1.901	0.002	1.263 - 2.862	1.962	0.003	1.253 - 3.074						
Male (Reference)	188												
Study area													
Urban	154	1.206	0.372	0.799 - 1.818	1.605	0.046	1.008 - 2.556						
Rural (Reference)	224												

Three separate multiple logistic regression models were developed for all respondents, only for female respondents and only for male respondents which showed the following (Table 5.4.5.1 and Table 5.4.5.1):

- PLHA with changed/new/no job status had 1.5 times more chances of becoming underweight when compared to the same job status (*statistically non-significant, p=0.170, OR= 1.518, 95% CI: 0.837 - 2.752*).

- PLHA with low or no income had 1.918 times more chances of becoming underweight when compared to those with a better/improved income (*statistically significant, p=0.002, OR= 1.918, 95% CI: 1.268 - 2.901*).

- PLHA with poor QOL after 1 year had almost 3 times more chances of becoming underweight compared to those who had good/excellent QOL status (*statistically significant, p = 0.005, OR =2.688, 95% CI: 1.345 - 5.372*). Multivariable regression analysis showed a similar association (*p=0.033, AOR =2.238, 95% CI: 1.065 - 4.700*).

- PLHA with food insecurity at the end of one year had 2.056 times more chances of becoming underweight when compared to those with decent food security (*statistically significant, p=0.001, OR= 2.056, 95% CI: 1.363 - 3.099*). Multivariable regression analysis showed a similar association (*AOR 1.763, p=0.013, 95% CI :1.125 - 2.762*).

- PLHA with a health score difference <5 after 1 year had 3.376 times more chances of becoming underweight than those with health score difference <5 after 1 year (*statistically significant, p = 0.0001, OR=3.376, 95% CI: 2.171 - 5.252*). The same was true on multivariable regression analysis also (*AOR 3.280, p=0.0001, 95% CI: 2.065 - 5.211*).

- PLHA with anaemia at the end of one year had 2.690 times more chances of becoming underweight when compared to the same/improved Hb% (*statistically significant,*

p=0.001, OR=2.690, 95% CI: 1.526 - 4.741).

Thus, No or same Job, decreased or no income, food insecurity, poor quality of life, decreased level of Hb%, low before-after perceived health status, after 1 year of ART were significant predictors of low nutrition status i.e. decreased BMI or underweight. Also, female respondents were significantly at higher risk of low nutrition status while on ART. Hence gender-specific separate models for female and male respondents were developed.

Gender as an influencing factor for undernutrition in PLHA on ART

Male participants with poor/no income had 4-times higher chances of being underweight when compared to females (*OR=4.036, p=0.0001, 95% CI: 1.873 - 8.695*). Female participants had 6 times and 2.3 times more chances of being underweight with poor QOL (*OR=6.040, p=0.00795 % CI : 1.636 - 22.294*) and food insecurity (*OR=2.390, p=0.008,95% CI 1.255 - 4.550*) respectively when compared to males. Overall, female PLHA had 1.901 times higher chances of being underweight than male PLHA (*statistically significant, p=0.002*) (Table 5.4.5.1 and Table 5.4.5.1). On multivariable regression analysis a similar association was observed (*OR=1.962, p=0.033*). Thus, food insecurity and perceived poor quality of life are significant predictors of low nutrition status in female respondents while decreased or no income is the main predictor for low nutrition status of male respondents.

5.4.6 *Discussion*

Although easy availability of HAART has reduced the morbidity and mortality among PLHA significantly, the problem of undernutrition, weight loss persists to a great extent which in turn increases the risk of early mortality. Major factor for such indirect mortality and morbidity is through possible intermediate pathway due to poor immune reconstitution secondary to undernutrition as per Sicotte M *et al.,* [110] based on his systematic review on nutrition and HIV

patients' articles. Socio-demographic factors studied in our study play a vital role in maintaining the nutritional status of, which were neglected. Except for Free ART and intermittent counselling, PLHA did not receive any nutritional assistance coupled with perceived work environment stigma, which significantly affected the nutritional status of PLHA with females being more affected, especially being a housewife and cultural issues.

We could not find any other prospective study which compared the associations of nutritional status and all these factors over one year in the Indian context, in this regard, our study is a novel one. In a prospective study carried out in two West African cohorts by Sicotte M et al., [110] low Hb%, low albumin, low CD4 count were associated with undernutrition at baseline. Anaemia was associated with low CD4 counts and female sex. With treatment, although there was a gain in BMI but at the end of one year, malnutrition persisted in both the cohorts, and were associated with low Hb%, low Albumin and those who had low BMI at baseline. The authors concluded that malnutrition was with negative clinical and treatment outcome and HAART alone may not be enough to address malnutrition in the long run among PLHA.

Various other cross-sectional/retrospective studies carried out across the world showed various levels of undernutrition among PLHA on ART and their association. In one of the retrospective study of 08 years in Senegal (Benzekri NA *et al*) [108] and crossectional study in Ethiopia (Daka DW et al) [107], the authors showed both female and male undernutrition was associated with CD4 count less than 200 and WHO clinical stage 3,4 while in our study even if PLHA were in the better clinical stage and better CD4 count, undernutrition was high even after one year. Benzekri NA *et al.,* [108] based on their findings suggested integrating nutritional programs with HIV programs and the most effective strategies to be incorporated while dealing with men versus women. While a study carried out by Khatri *et al.,* [109] in Nepal showed that after multiple

linear regression analysis, age, male, married, business occupation, Hb% level and ART duration were significantly associated with BMI.

Sachdeva RK *et al.,* [6] in North India showed that it was basically the low-calorie intake, lower than the recommended average intake, which was correlated with lower nutritional status and recommended to increase access to nutritious high-quality diet to PLHA. The study findings correlate with our results too, with the majority having dietary inadequacy; however, our study did not find a statistically significant association between dietary diversity and undernutrition as compared with others. Similarly, Anand D *et al.,* [104] also emphasized the intake of poor quality of diet which could not meet even two-thirds of ICMR standards, was responsible for high undernutrition levels among PLHA (40%). Even in countries with high HIV prevalence, studies carried out by Isabirye N *et al.,* [114] and Hadgu TH *et al.,* [106] showed low consumption of quality diet with lesser protective nutrients corelating with high levels of undernutrition.

Hadgu TH *et al.,* [106] in a cross-sectional study, showed that the independent predictors of undernutrition were food insecurity, inadequate dietary diversity, anaemia and absence of nutritional support, which correlates with our study too. Similarly, a recent study by Hussein FM *et al.,* [126] showed that household dietary diversity and food insecurity were proxy indicators for poor nutritional status among PLHA. Heylen E *et al.,* [121] in South Indians also showed that both PLHA men and women had moderate to severe food insecurity leading to poor QOL and psychological issues. Similarly, another study by Tesfaye M *et al.,* [77] in Ethiopia showed severe food insecurity associated with mental disorders and were both corelated with low QOL. Even in developing countries with a high prevalence of HIV, authors have showed in independent studies that food insecurity has been associated with being single, illiterate, anaemia and inadequate

dietary diversity and recommended HIV programs to integrate food and nutritional interventions within care support and treatment (Oluma A *et al*) [61].

Fahey CA *et al.,* [127] also in Tanzania showed that severe food insecurity decreased with food and cash incentive rather than just standard of care facilities and recommended the same at the initiation of treatment where cash and food is needed at the highest level as it would mitigate food insecurity and also help in ART adherence. Even in developed countries, food insecurity has been observed to a great extent by various authors. In a study by Normen L *et al.,* [64] in Canada, 27% were food insecure without hunger and 21% of them were food insecure with hunger. In both categories, women were significantly affected, and strongest predictors were low income, low education, the house being shared with children, unemployment. Even in Australia, Langton A *et al.,* [63] showed that 47% of PLHA reported food insecurity and was higher in PLHA with unemployment, females, lower perceived health status and detectable or unknown viral load, the findings of this study are similar to our study. In one of the longitudinal studies, in San Francisco by Weiser AD *et al.,* [122] after a follow up of median 22 months, 55% were food insecure and were associated with poor HIV outcomes with increasing odds of ART non-adherence and incomplete viral load suppression. Thus, various types of studies carried out across the world, both in poor developing and developed nations, recommend efforts to integrate dietary and other measures directed against food insecurity which will go a long way in improving the health outcomes in PLHA.

Concerning QOL, various studies carried out across the world indicate positive association of QOL with nutritional status. Carvalho BFD *et al.,* [67] showed PLHA with less QOL were seen with inadequate energy intakes and reported weight loss. Similarly, Sackey J *et al.,* [128] and Tesfaye M *et al.,* [77] showed a positive association of QOL with nutritional status and food insecurity. They

elucidated the need for a longitudinal study, which our study being prospective, proved the significant association of nutritional status with QOL. Even in another observational study in India by Anand D *et al.,* [79] showed PLHA with lower BMI also had poor QOL, and various other studies by Tesfaye M *et al.,* [77] , Shriharsha C *et al.,* [81] and Anuradha *et al.,* [82] emphasized the importance of QOL among PLHA which otherwise would severely affect their mental wellbeing, and PLHA can go into depression and thus a vicious cycle to start with poor nutritional status, depression and QOL.

Concerning anaemia, our study showed statistically significant association with undernutrition, wherein low Hb% at the end of one year of ART is associated with lower BMI than compared to the same/improved Hb%. Similarly, various studies carried out across the world have showed a similar association with anaemia. Ageru TA *et al.,* [111] in their study showed high prevalence of Anaemia (37%) and most important factors associated were low BMI, Longer HIV duration, CD4 count less than 200 and infection with intestinal parasites. Similarly, Gebremedhin KB *et al.,* [112] showed positive association of Aneamia and nutritional status along with gender, platelet count, occupation and WHO clinical stage of HIV/AIDS. Aynalem YA *et al.,* [113] in Ethiopia showed an anaemia prevalence of 26.2% and a positive association with nutritional status and past opportunistic infections. All these authors, emphasized the need of periodic monitoring of Hb% levels, routine nutritional status, CD4 counts and continuous counselling to overcome anaemia at the earliest stage and increase the effectiveness of ART.

5.4.7 *Cooking, food consumption and WaSH (Water, sanitation and hygiene) practices*

<p align="center">Table 5.4.7 : WaSH practices of study subjects</p>

	Frequency	Percent
Water processing method used		
Aquaguard	2	0.5
Boil	25	6.6
Filter	64	16.9
Water used without any pretreatment	287	75.9
Type of sanitary facility used		
Open air defecation	14	3.7
Own Latrine at home	253	66.9
Public/ shared latrine	111	29.4
Handwashing status		
Handwashing after toilet use (Yes)	377	99.
Handwashing before food consumption (Yes)	377	99.7
Materials used for hand Washing		
Ash and Soil	4	1
Soap and water	298	78.8
Water only	76	20.1
Total	378	100.0

5.4.7.1 *WaSH practices of study participants:*

PLHA would be already in an immune compromised state where in, acquiring opportunistic infections are very high through water and food. It is estimated that diarrhoea rates are 2-6 times and persistent diarrhoea two times higher among PLHA than in HIV negative persons[84,85]. These opportunistic infections degrade the Quality of life and make the life miserable for PLHA. Therefore access to good quantity and quality of Water, Sanitation (Proper handling and disposal of all hazardous wastes) and good Hygiene practices, especially hand Washing in particular, are a must for PLHA to lead a good quality of life so that they are protected from common source of

opportunistic infections. While developed countries have started to integrate WaSH practices into HIV/AIDS programme, at the same time most of the developing countries are yet to integrate. At the household level, adequate WaSH practices have broader socio-economic impacts [(129).] Hence in our study, we tried to explore WaSH practices among our study population (Table 5.4.7)

Water usage – Access to good quality of water in good quantity is a must for all PLHA. Our study participants said none of them faced any deficiency of water in terms of quantity or in terms of quality. When asked about the water processing method, 76% of them told they do not treat/process the water supplied to them. In contrast, only a few PLHA told they would filter (17%), boil (7%) and use aquaguard (1%). These results show the risk faced by our study participants by drinking water without any filtration/ UV radiation inturn leading them to several waterborne diseases.

Sanitation practices – Safe disposal of faeces is one of the most important aspects of sanitation. Accordingly, HIV/AIDS programs should support good sanitation practices as water and foodborne infections can further deteriorate PLHA health. It is also essential that PLHA who do not have bowel control should be aware of safe handling and disposal of faeces in hospital and community setting. In our study, the majority (67%) had their latrines, and while 29% of them were using public latrines and its hygienic sanitation was a concern for them and 4% were still practising open-air defecation in rural areas, which is a risk for them and the community.

Handwashing - Handwashing as often called as Do-It your vaccine for preventing many water and food borne diseases[130] is an important determinant for PLHA to prevent opportunistic infections and maintain their Quality of life. Various studies have shown beneficial effects of handwashing in reducing / occurrence of infections/ diarrheal episodes[89,131]. In our study, almost

all study participants were handwashing after toilet use and handwashing before consuming food. However, when asked about the materials used for Handwashing, the majority (79%) told they used soap and water, while 20% were using only water, soil and water (1%) and ash and water (1%) which was a concern.

5.4.7.2 *Cooking practices -* Good Cooking and storing food practices helps PLHA households to increase the nutritional quality of their food as well as prevent food and water-borne diseases. In our study, 87% of households cooked their food twice and consumed it thrice a day, while 4% prepared thrice. 10% of them cooked only once and consumed thrice a day which may affect the health of individual if not stored properly or temperature is not maintained. One positive practice observed by almost all was, they kept food covered after preparing.

5.4.7.3 *Food consumption practices -* These are of vital importance both while eating outside the house as well as inside. Usually, consumption of leftover food of the previous night is the practice in rural households, but consuming over-night food is of high risk for PLHA since the chances of it getting contamination and rotten is very high. Although 87% of PLHA cooked fresh food twice daily, 56% practised consumption of leftover food of the previous night which was a concern. A majority (54%), did not consume street food while remaining said that they used to consume street food. But majority (59%) said they did not follow the habit of checking hygiene or sanitation of hotel where they used to consume food while, the remaining 41% did not check the hotel before ordering the food (Table 5.4.7.3). Although being of a high biological value, milk simultaneously is a potential substrate for developing microorganisms if not appropriately treated. Therefore, the source of milk and its processing plays an important role, especially among PLHA. In our study, the majority (50%) bought packaged milk while 40.9% brought from unpasteurized Dairy.

However, 91% said that they boiled the milk before consumption and there is a need for remaining to educate about using pasteurized and boiling of milk before consumption.

Some of the WaSH parameters in our study showed alarming practices which needed to be changed. The most important factor which would have an impact, is the awareness of the individual and the households regarding the good practices, although social and cultural factors do influence the practices. These practices are the "Art of preserving life" in this century where in communicable diseases are at high, especially in developing nations. With the COVID 19 Pandemic, and in water and foodborne endemic disease areas, these WaSH and Cooking, food consumption practices would play a significant role in maintaining the nutritional status of PLHA and thus affecting the Quality of life. So, these factors should not be neglected and should be integrated into HIV programs for synergistic benefit.

In India, we could find only a few articles focusing on WaSH practices among PLHA. As per Cunha GH *et al.,* [132] after integrative review of the literature found only 16 articles published on these practices which include eight in European countries, two in Brazil, 5 in the United States and only one in India, emphasizing the need for in-depth research and integration of these practices in HIV/AIDS program. Various articles across the world from time to time have highlighted the importance of Handwashing before eating food and after defecation[133-135,89,131,137], avoid eating outside home with questionable cleanliness[137], use water filtered, boiled or after chlorination[138,133,134, 136,137], food not to be kept open for longer duration (> 2 hours) [137], not to consume unpasteurized or unprocessed raw milk[137,139], avoid eating food from street vendors[84,138] and have own household sewage system[134,136,84]. All these factors play a very significant role in

HIV/AIDS patients who are already immunocompromised and have high chances of opportunistic infections getting through.

On statistical analysis, hygiene and sanitation factors had no statistically significant association with the nutritional status of study participants. However, all these aspects play an essential role on nutritional status of PLHA and act synergistically in improving QOL and thereby reduce chances of opportunistic infections especially in PLHA with reduced CD4 count and increased viral load. Schilling KA et al., in 2018[140] showed findings of no statistical association of WaSH practices between HIV positive and HIV negative persons. However, there was an association between HIV positive with known HIV status of fewer than 30 days duration and more than 30 days duration, emphasising that people with known HIV status for more than 30days followed effective water treatment methods and storage techniques. The authors here tried to see the effectiveness of HIV program promoting positive WaSH practices and behaviour among PLHA in Kenya which they have started. Authors in this study also discussed how they have implemented the WaSH practices so effectively, firstly by stringent pre and post-test counselling towards WaSH practice. Secondly, by integrating WaSH practices into HIV program including providing basic care packages to PLHA[141-143] like household water treatment products and soap through local NGOs. However, in our setup, still PLHA have not given much importance to WaSH practices, and there is a need to incorporate and integrate various measures into our programs so that nutritional status and QOL of LHAs are maintained.

In another study carried out by Yallew WW et al., [89] in Ethiopia, 67% of households had unimproved sanitation status, 52% of them had poor hygiene practices, and 43% had unimproved water status when they studied about WaSH practices among PLHA in-home care system. They also found statistically significant findings of diarrhoea with water status, education and presence

of latrine with sanitations status, hand Washing device presence, economic reasons for soap affordability with hygiene practices. The authors concluded education and economic factors improvement for better WaSH practices among PLHA which our study participants are also in need and HIV programs should include measures to improve these factors.

Table 5.4.7.3 : Cooking and food consumption practices of study subjects

	Frequency	Percent
Food kept covered after preparing		
No	1	0.3%
Yes	377	99.7%
How many times cooking food		
once	36	9.5%
twice	328	86.8%
thrice	14	3.7%
Leftover food from previous night consumed		
No	165	43.7%
Yes	213	56.3%
Street food intake		
No	203	53.8%
Yes	175	46.2%
Check hygiene/ sanitation of hotels before eating		
No	223	58.9%
Yes	155	41.1%
Source of Milk (multiple responses)		
Dairy, unpasteurized	153	40.9%
No intake of milk	33	8.8%
Packaged milk	188	50.3%
Boiling Milk before consumption	340	90.9%

Based on the findings of our study and discussion with various studies carried across the world, the following conceptual frame (Figure 5.4.7.3) has been prepared, which shows various factors

influencing the nutritional status of PLHA and the complex interplay of all these pointing towards the action needed at multiple levels.

Figure 5.4.7.3 : Conceptual framework showing various factors influencing PLHA nutritional status
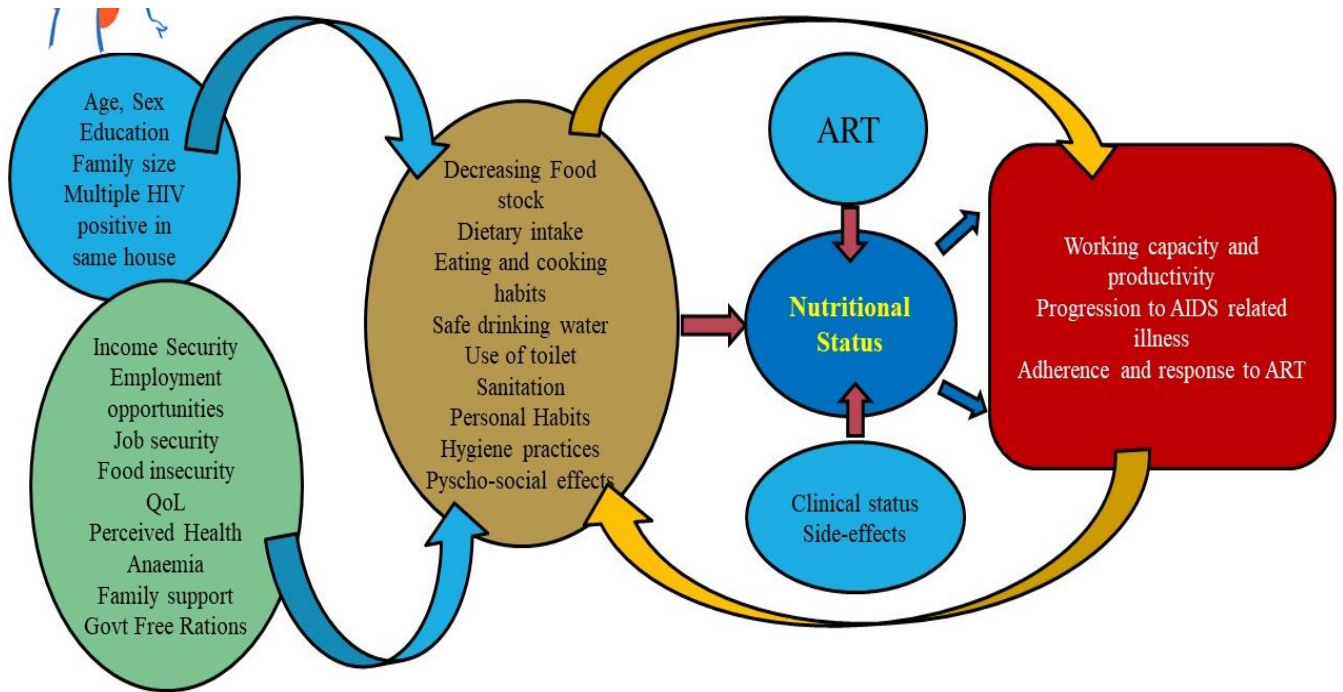
Across various studies we discussed, the majority of them showed undernutrition to be associated with food insecurity, income insecurity, job insecurity, QOL, health status, Hb% level but an essential factor to note was these studies also said deteriorating clinical status (Stage 3 and 4), opportunistic infections and side effects also influenced nutritional status. While in our study in spite of continuous counselling, monitoring and ART for one year, the undernutrition levels among study participants were at 35% without much serious opportunistic infections (11%), side effects (14%), almost all were above clinical stage 3 and 4 with ART adherence of >95%. All these findings and discussion emphasize that, in spite of good clinical-stage, lower OIs, side effects and good adherence rate to ART, chances of staying undernourished remain high as various other

socio-demographic factors including Job insecurity, food insecurity, income security, QOL, WaSH practices, food consumption pattern and nutritional support have a huge impact on nutritional status. Therefore, interventions directed towards reducing undernutrition is the need of the hour and all efforts be made at all levels, to address various factors as shown in the conceptual framework to increase the quality of life of PLHA and reduce morbidity and mortality.

5.5.1 *Objective 3 - Assessment of selected NCD risk factors among the study participants*

Table 5.5.1: NCD Risk profile among study subjects

	Baseline at the start of study)	**After one year**
Smoking	20 (5.3%)	08 (2.1%)
Tobacco	114 (30.5%)	98 (26.2%)
Alcohol	55 (14.7%)	31(8.31%)
Yoga	0 (0%)	02 (0.5%)
Physical activity	12 (3.2%)	36 (9.7%)
Overweight	43 (11.4%)	53 (14%)
Obese	57 (15.1%)	66 (17.5%)

Figure 5.5.1.1: Distribution of NCD Risk profile among study subjects at baseline and after one year

	Smoking	Tobacco	Alcohol	Yoga	Physical activity	Overweight	Obese
Baseline	5.30%	30.50%	14.70%	0%	3.20%	11.40%	15.10%
After one year	2.10%	26.20%	8.31%	0.50%	9.70%	14%	17.50%
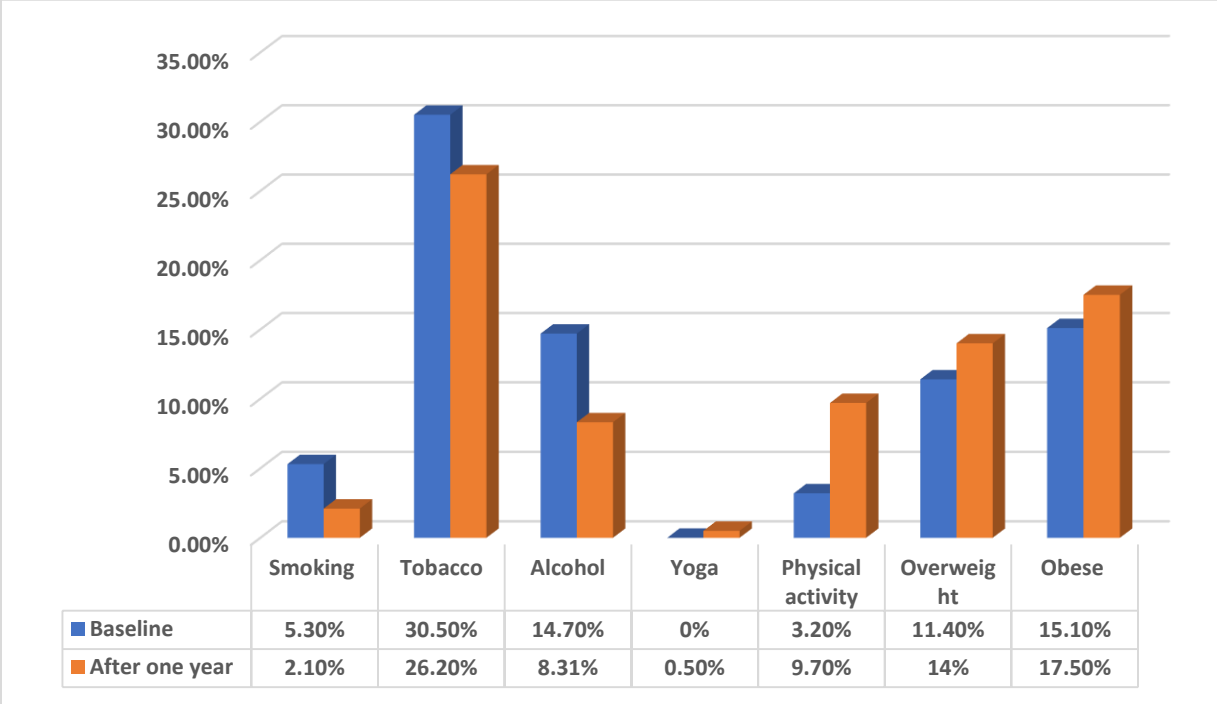
Non-Communicable Diseases (NCDs) burden has been increasing all over the world and expected to rise dramatically over next 20 years especially in low and mid-income countries[97]. Similarly, NCDs are also rising among PLHA due to various reasons like HAART which has made HIV a chronically managed disease and increased their life span, side effects of HAART causing heart disease risk and altered metabolism also[97]. HIV itself has increased the risk of cancers because of opportunistic infections. Apart from the increase in lifespan and use of HAART among PLHA, NCDs are occurring because of chronic immune action, medication side effects, co-infection & the aging process itself[97] coupled with modifiable risk factors like smoking, alcohol, tobacco chewing and lack of physical activity. In our study we studied selective NCD risk factors profile to have a baseline levels of these risk factors and at the end of the study, to monitor and document

the progress and occurrence of NCDs in future. Our study showed that although PLHA did reduce smoking, tobacco and alcohol consumption from baseline 5%, 31% and 15%, to after one year 2%, 26% and 8% respectively. Still, Smoking and alcohol consumption remained moderately high despite continuous counselling at ART centers. Although few PLHA started yoga (1%) and some form of physical activity (10%), the overweight and obesity prevalence increased from baseline 11% and 15% to 14% and 18% (Table 5.5.1 and Figure 5.5.1.1), which was much high when compared to the general population in India, where the prevalence of obesity is 15% (women) and 11% (men) (144).

As per the International Diabetes Federation criteria for South Asians, a waist circumference of > 90cm for Men and > 80cm for Women is considered abnormal. In our study, 24% of PLHA had abnormal waist circumference, while we could not measure waist circumference in 20% of them, due to lack of time and few ladies didn't give consent to measure. The increased waist circumference levels may be attributed to their lifestyle and NCD risk factors if not properly educated about the risks and lifestyle modifications, this number may increase significantly in the coming years. It might be the tip of iceberg, as few PLHA were hesitant in disclosing their habits and probably didn't disclose the same because of unwilling to discontinue the habits and with fear of spending more time for counselling.

NCDs risk factors, HIV infections, ART and socio-demographic factors act in a complex way to alter the PLHA health status[98]. These complex webs of causation are primarily based on high-income countries data, while in developing nations, data regarding NCDs and their risk factors are largely unavailable. Our findings are consistent with a study carried out by

Mathebula RL *et. Al.,* [46] in African province wherein overweight and obesity rates increased from baseline 18% and 11% to 21% and 20% respectively within 3.6 years, while our study period was only one year, indicating that rates of overweight and obesity observed, may still go up in coming years if corrective measures are not undertaken by individuals and integrated into ART care and counselling. Similarly, the overall prevalence of Overweight and obesity as per cutoff levels of waist circumference for Indians was 32% which was higher than observed in our study (24%). Smoking and alcohol consumption were 11% and 22% which was higher compared to our study. Another study in Tanzania by Kagaruki G *et. al.,* [145] also showed an increased prevalence of overweight/obesity (61%) and abnormal waist circumference (61%) than compared to a baseline of 39% and 38% respectively, which is much higher than our study within the same period. The authors also concluded that males, aged >40 years, abnormal waist circumference, and overweight/obesity were strong predictors for hypertension. NCD risk factors were significantly higher among those on ART than compared to not on ART.

Tate T *et al.,* [146] in Birmingham in a study on among 681 patients, showed 44% PLHA were overweight/obese with a mean baseline BMI of 25.4+_6.1 %. There was 20% increase in overweight/obese rate from normal after two years, which was quite high compared to our study. In one more study in South Africa by Heerden AV *et al.,* [147] carried out on community with a high burden of HIV 71% were overweight/obese and 80% of both HIV positive, and HIV negative had one or more of NCDs risk factors. In one of the largest study in sub-Saharan Africa in 2019, from 44 countries by Coetzee *et al.,* [148], the prevalence of overweight/obesity was 14.7% increased among PLHA than compared to normal people, and those who were on ART were 14% increased rates of overweight/obesity than compared to those, not on ART. All these studies have highlighted

the importance of NCDs risk factor screening and early detection and have recommended interventions to tackle and control the occurrence of NCDs among PLHA.

Figure 5.5.1.2: Overweight and Obesity status of study subjects
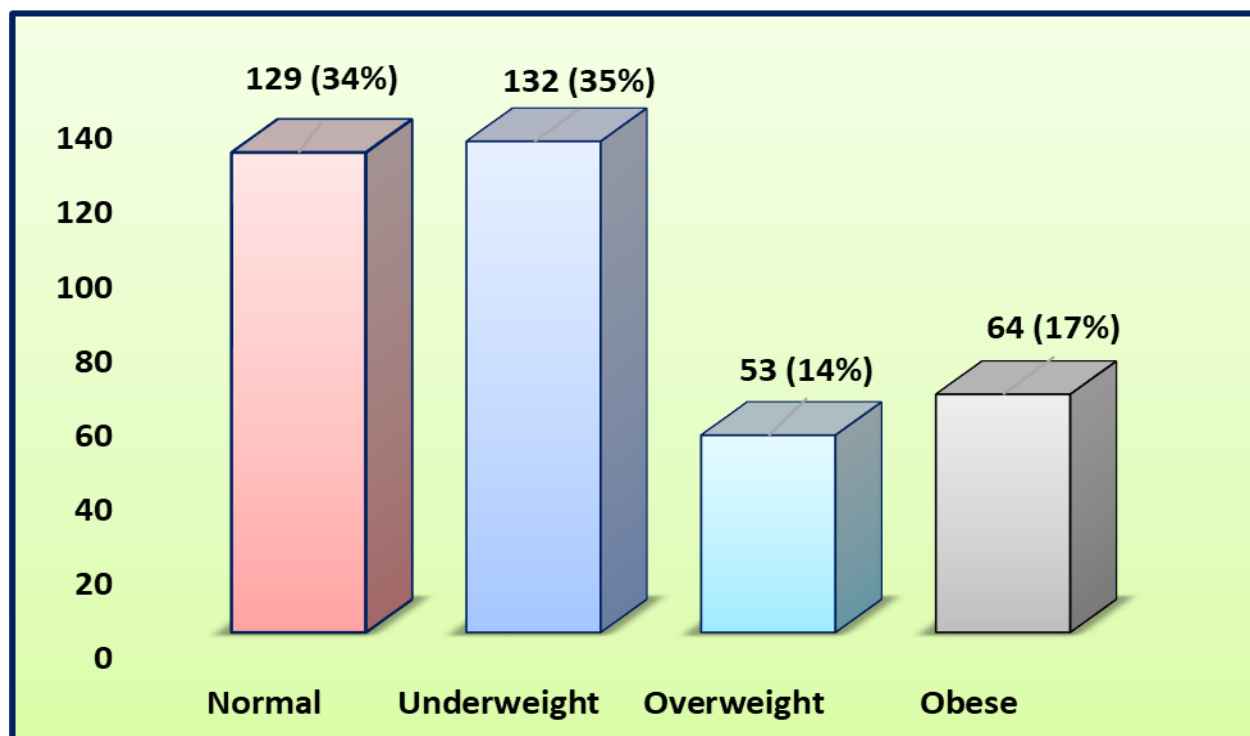
5.5.2 *Undernutrition and Overweight/Obesity*

Since the origin, HIV is known for HIV wasting syndrome, an AIDS-defining condition. But in the last two decades, significant improvements in treatment, care of PLHA and with the advent of newer HAARTs, wasting syndrome is not seen so frequently associated with HIV as before, instead, non-communicable diseases, including obesity are being seen more commonly associated. In fact, at a global scale, an estimated 41 million NCD related deaths occur annually as per WHO[149]. So, HIV has now become double-edged sword, with one side undernutrition/wasting and on the other side overweight/Obesity. Thus, nutritional factors are essential for PLHA for their health outcomes. Both undernutrition and obesity have multifactorial factors with chronic innate and adaptive immune activation mechanisms, which have been implicated in the pathogenesis of multiple comorbidities and impaired immune recovery during ART, as shown in Figure[150] 5.5F.2. Our study looked at both types of abnormal nutritional status in PLHA i.e., undernutrition and overweight/obesity, by following them up prospectively for one year (Table 5.3.1.1).

Necessary actions as discussed above are the need of the hour and to be incorporated into our HIV/AIDS programme to comprehensively target ill-health among PLHA, to mitigate the undernutrition and obesity related adverse effects on chronic immune activation and maintain their health outcomes at the highest level possible.

Figure 5.5.2: Malnutrition and obesity-related factors potentially affecting chronic immune activation among PLHA

Innate immunity:
• Reduced GI mucosal integrity
• Higher microbial translocation
• Villous blunting and local inflammation
• Lower secretory IgA
• Lower eosinophils and NK cells

Adaptive immunity:
• Lower total lymphocytes
• Reduced T cell proliferative response
• Higher T_H2-type CD4+ cell polarization
• Lower T_H1 cell IL-2 and INF-γ expression
• Impaired delayed hypersensitivity response

Potential interventions:
• Food assistance / macronutrient supplements
• Livelihood support / cash transfers
• Clean water & sanitation programs to reduce environmental pathogens
• Expanded HIV testing and earlier treatment

Innate immunity:
• Higher circulating IL-6 and other cytokines produced by adipocytes
• M1 inflammatory macrophage and T_H17 CD4+ T cell polarization in adipose tissue
• Leptin (adipokine) promotes macrophage TNF-α, IL-6 and IL-12 expression

Adaptive immunity:
• More robust CD4+ cell recovery on antiretroviral therapy at higher BMI
• Increased peripheral T cells, T cell activation, and T_H1-type CD4+ cell polarization
• Leptin (an adipokine produced by adipocytes) promotes CD4+ T cell proliferation and T_H1 polarization *in vitro*

Potential Interventions:
• Weight loss and exercise programs
• Gastric bypass
• Growth-hormone-releasing hormone (Tesamorelin)

SUMMARY

6.1 *Summary*

Our study showed high undernutrition levels among PLHA despite free ART for one year resulting from a complex web of socio-demographic factors including HIV, undernutrition, food insecurity, job insecurity, income insecurity and lower health status. All these factors need to be taken care of if we want PLHA to lead a healthy life with good nutritional status. The following characteristics are hereby summarized supporting the inferences from our study: -

- With the mean age of the study cohort of 41yrs, and even after one year of treatment, undernutrition in our study was at 35%, anaemia at 60%, low albumin at 13%, low total protein at 14%, which were higher in spite of regular treatment and monitoring.72% were consuming an <u>inadequate diet.</u>

- QoL in our study was assessed by using the WHO QoL Brief, which showed that the majority, 57%, had a poor QoL index, while 32% and 12% had good and excellent QoL indices, respectively.

- In our study, we assessed food insecurity utilizing household food insecurity access scale (HFIAS), wherein the majority, 53% showed food insecurity.

- Perceived health status was assessed using EQ 5D 3L visual analogue scale (VAS), which showed majority 62% had after effect health status categorized as less-than-or-equal-to 5, indicating no significant improvement in health status compared to the baseline.

- PLHA with changed/new/no job status had 1.5 times more chances of becoming

underweight when compared to same job status (*statistically non-significant, p=0.170, OR= 1.518*).

- PLHA with low or no income had 1.918 times more chances of becoming underweight when compared to those with a better/improved income (*statistically significant, p=0.002, OR= 1.918*).

- PLHA with poor QoL after 1 year had 2.688 times more chances of becoming underweight compared to those who had good/excellent QOL status (*statistically significant, p = 0.005, OR =2.688*). Multivariable regression analysis showed a similar association (*AOR =2.238, p=0.033*).

- PLHA with food insecurity at the end one year had 2.056 times more chances of becoming underweight when compared to those with decent food security (*statistically significant, p=0.001, OR= 2.056*). Multivariable regression analysis showed a similar association (*AOR 1.763, p=0.013*).

- PLHA with a health score difference <5 after 1 year had 3.376 times more chances of becoming underweight than those with health score difference <5 after 1 year (*statistically significant, p = 0.0001, OR=3.376*). The same was true on multivariable regression analysis also (*AOR 3.280, p=0.0001*).

- PLHA with anaemia at the end of one year had 2.690 times more chances of becoming underweight when compared to same/improved Hb% (*statistically significant, p=0.001, OR=2.690*).

- ***Thus, No or same Job, decreased or no income, food insecurity, poor quality of life, decreased level of Hb%, low before-after perceived health status, after 1 year of ART were significant predictors of low nutrition status i.e. BMI decreased or***

underweight. Also, female respondents were significantly at higher risk of low nutrition status while on ART. Majority of the PLHA practiced wrong cooking/poor eating habits and consumed unpasteurized milk.

- The majority of them consumed water not made safe and did not use soap for handwashing. Thus, some of the WaSH and food consumption parameters in our study showed alarming practices which needed to be changed. These practices are the "Art of preserving life" in this century where in communicable diseases are at high, especially in developing nations with the COVID 19 Pandemic and various other local water and foodborne diseases on high levels. Although hygiene and sanitation factors had no statistically significant association with the nutritional status, these aspects play an important role on nutritional status and act synergistically in improving QoL and thereby reduce chances of opportunistic infections, especially in PLHA with reduced CD4 count and increased viral load.

- About 31% of the subjects were found to be overweight/obese, with 32% being tobacco users and 8% alcohol drinkers, flagging the need to implement preventive measures for NCDs even in PLHAs.

Our study discussed both the versions of nutrition - undernutrition and overweight/obesity, which acts as a double-edged sword for PLHA's health. **Significant predictors of undernutrition among PLHA after one year as per our study findings, are socio-demographic factors like Poor/no income, job insecurity, food insecurity, poor QoL, anaemia at the end of one year of ART, female gender and those living in urban areas**. Necessary actions as discussed in recommendations below, are the need of the hour and to be incorporated into our HIV/AIDS

programme to comprehensively target ill-health among PLHA and to mitigate the undernutrition/obesity adverse effects on chronic immune activation and maintain their health outcomes at the highest level possible.

6.2 *Conclusion*

Undernutrition has a multidimensional effect on HIV disease progression. Undernutrition coupled with a compromised immune system increases the frequency, severity, duration of opportunistic infections, the symptoms of which accelerate increase weight loss, and thereby cascading a vicious cycle. In this study, despite free of cost ART being made available for one year, still (35%) were underweight,13% had low albumin, low total protein (14%), 72% had inadequate diet. Factors such as food insecurity (53%), poor QoL (57%), poor before-and-after health status (62%) and poor WaSH practices were associated with undernutrition in PLHA. **As per our study, significant predictors of undernutrition among PLHA after one year, are socio-demographic factors like Poor/no income, job insecurity, food insecurity, poor QoL, anaemia at the end of one year of ART, female gender and those living in urban areas**. Synergistic effects of malnutrition, food insecurity, poor diet and health status influence poor outcomes in the already compromised household conditions due to increased financial constraints with superimposed emotional breakdown. Hence, even a tiny fraction in weight loss would result in significant morbidity and decreased survival rate among PLHA. Thus, **proactive measures as mentioned in recommendations below need to be taken at high priority.**

Although most PLHA still practice poor cooking/eating habits, consume unpasteurized milk from dairy (41%), consume raw water (76%), and do not use soap (22%) for handwashing, no statistical

significance was observed on bivariate analysis. However, it is to be noted that all the afore-mentioned factors act synergistically with other factors to affect the holistic health of PLHA.

On the one hand, undernutrition is of vital concern regarding the health of PLHA. With the development of quality ART, the risk of non-communicable diseases has apparently increased according to the current estimates available in the literature. This is in concurrence, with the findings from our study with overweight/obesity prevalence being 31%, and tobacco and alcohol usage at 32% and 9%, respectively. These findings **indicate the incorporation of early screening for NCD risk factors among PLHA to prevent and manage the same at the earliest before it can aggravate the already compromised immune status in these subjects**.

6.3 *Recommendations (Objective 4)*

- Consistent and proper nutritional assessment, regular screening and management of anaemia and perceived health status are must, to identify any derangement at the earliest and measures taken. Immediate measures concerning nutritional support, especially counselling, dietary supplementation, economical packages to procure good quality food, and monitoring, needs to be implemented at ART centres.

- Counselling and possible Government support measures, including the law concerning job security, food security, measures to improve QOL of PLHAs need to be incorporated and integrated with the long term goals of the NACO program.

- Gender-sensitive and area-wise (urban/rural) directed nutrition interventions need to be planned.

- IEC activities (continuous and regular) that focus on improving awareness level on WaSH practices need to be promoted and integrated into HIV program, including providing basic

care packages to PLHA like household water treatment products and soap etc.

- Screening of NCD risk factors in this population at an early stage of start of ART needs to be emphasized and implemented at the earliest. Appropriate behaviour change communication (BCC) for maintaining a healthy lifestyle and effective psycho-social counselling should be undertaken and responsibility, accountability assigned to all concerned.

6.4 *Limitations*

The most significant limitation is the HIV/AIDS disease and associated stigma itself. Most of the patients cover the face and come to the ART centres in a hidden way, try to avoid much interaction with others so that they don't get exposed of their HIV status. With this, informing them about the need for the study and recruit them into the study after motivating and convincing them to spend time with us for data collection was a huge challenge and a limitation. Because of these challenges following limitations were encountered.

- *Missing Data*: While the majority gave blood at baseline but on follow up they could not spare much time. So only 217 out of 378 subjects were able to give blood during follow up assessment. In fact, at the baseline, total cholesterol and lipid profile was also taken from a few PLHA, but since it required fasting sample, the majority of PLHA could not come during the early morning. In fact, the majority of PLHA used to work till 1100hrs and then come to the ART centre while blood testing samples were taken till 1145hrs only. So, sample collection was missed in a few, and we did not insist on PLHA as for them, their time was precious.

- *Absence of on ground assessment*: In order to see the WaSH and food consumption practices, we intended to visit the PLHA house for on ground assessment. But almost all refused to give consent to visit the place fearing stigma and thinking that neighbours may come to know about their status. So only questionnaire-based data was used for analysis.

- *Missing Waist circumference data*: Waist circumference was collected at baseline and at one year-end upon 80% of the study participants while others could not spare more time for data collection.

- *Onetime assessment*: QoL and Food insecurity scale were able to be assessed only at one time, that is, after one year. Ideally, we intended to collect data, both at baseline and at the end of one year. But at baseline, when ART was started, most PLHA did not have must interest to spend more time as their health and psychological wellbeing was not good. So, only after one-year data was used for analysis.

- *Questionnaire issues* : In order to avoid lengthy questionnaire and more time for data collection, few variables, although important, like blood pressure measurement , waist Hip ratio etc were not included in the questionnaire based on the pilot testing for the average time taken to complete data collection.

- *Attrition*: Overall, 430 participants were enrolled in the study and baseline data were collected from them. Only 378 remained till the end of the study period (13 months) and were included in the final analysis while the remaining 23 participants were lost to follow up, 22 expired and 07 transferred out. Even on telephonic conversation, loss to follow up PLHA did not respond properly, and thus they were not included in the data analysis.

However, the required number of participants as per the study sample size were present at the end of the study and hence included.

To carry out in-depth prospective study among PLHA is highly difficult task with more challenges because of time factor and various social issues, including stigma and discrimination. However, in our research we tried our best to make PLHA comfortable while collecting data and maintaining ethical protocols at all time. All PLHA including ART staff, were very happy that this research would give them lots of benefits and measures will be taken by the authorities to improve their health outcomes.

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BLDE (DEEMED TO BE UNIVERSITY)

PLAGIARISM VERIFICATION CERTIFICATE

1. Name of the Student: Dr Ravishekar N Hiremath Reg No: 13PHD010

2. Title of the Thesis: A PROSPECTIVE STUDY TO ASSESS THE FACTORS AFFECTING NUTRITIONAL STATUS OF PEOPLE LIVING WITH HIV/AIDS (PLHA) RECEIVING ANTI-RETROVIRAL THERAPY (ART)

3. Department: Community Medicine

4. Name of the Guide & Designation: Dr Shailaja S Patil, Professor &HOD

5. Name of the Co Guide & Designation: Dr DB Kadam, Professor and HOD (Retd)

The above thesis was verified for similarity detection. The report is as follows:
Software used: TURNITIN Date: 30.03.2021.
Similarity Index (%): One percent (1%) Total word Count: 21094
The report is attached for the review by the Student and Guide.
The plagiarism report of the above thesis has been reviewed by the undersigned.
The similarity index is below accepted norms.
The similarity index is above accepted norms, because of following reasons:
...The thesis may be considered for submission to the University. The software report is attached.

Signature of the Guide **Signature of Co-Guide** **Signature of Student**

Name & Designation **Name & Designation**

Verified by (Signature)

Name & Designation

<u>**ANNEXURE II**</u>

B.L.D.E. UNIVERSITY

(Declared vide notification No. F 9-37/2007-U 3 (A) Dated 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act,1956)

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

IEC Ref No-95/2014-15   November 15, 2014.

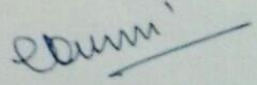### INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on 22nd September 2014 at 11 AM to scrutinize the Synopsis / Research projects of Postgraduate student / Undergraduate student / Faculty members of this University / college from ethical clearance point of view. After scrutiny the following original / corrected & revised version synopsis of the Thesis / Research project has been accorded Ethical Clearance.

Title ""A prospective study to assess the factors affecting nutritional status of people living with HIV/AIDS (PLHAS) receiving anti-retroviral therapy (ART)."

Name of PhD./ P. G. / U. G. Student / Faculty member. Dr.Ravishekar N Hiremath Department of Community Medicine.

Name of Guide :.Dr.Shailaja S.Patil .Professor Dept. of Community Medicine.

Dr. Sharada Metgud
Chairperson, I.E.C
BLDE University,
VIJAYAPUR – 586 103

Dr.G.V.Kulkarni
Secretary, I.E.C
BLDE University,
VIJAYAPUR – 586 103.

Member Secretary,
Institutional Ethical Committee,
BLDE University, BIJAPUR.

Following documents were placed before Ethical Committee for Scrutinization:

- Copy of Synopsis / Research project
- Copy of informed consent form

PERMISSION LETTER FROM NACO

T-11020/55/2013-NACO (R&D)
Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation

9th Floor, Chandralok Building,
36, Janpath, New Delhi-110001
Dated the 20th November, 2014

To,

Dr R.N. Hiremath,
Ph.D. Scholar,
Department of Community Medicine,
B.L.D.E.U. Sri. B.M. Patil Medical College
Bijapur- 03

Subject: Research Project entitled, 'Prospective study to assess the factors affecting nutritional status of people living with HIV/AIDS receiving ART' - regarding

Sir,

This is in reference to the request received from vide your letter no. nil, dated 26th October, 2014, for granting permission for undertaking the Ph.D thesis study at ART Centres from Pune District.
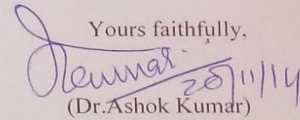
The proposal has been reviewed by R & D CST Divisions, NACO. Permission is herby accorded for undertaking this study, subject to the following conditions:

1. Copy of the modified proposal and Institutional Ethics Committee Clearance should be submitted to Maharashtra State AIDS Control Society before commencing the study
2. Copy of the final report may be submitted to NACO & Maharashtra State AIDS Control Society
3. Any publication out of this study will need to have prior NACO approval.

Entire expenditure for this study will be borne by the Ph.D. student and the institute/University undertaking this research. No technical or financial support will be provided by NACO/GOI or Maharashtra State AIDS Control Society.

In this regard, you may coordinate with the Project Director, Maharashtra State AIDS Control Society. Any adverse events observed during this study may please be communicated to NACO.

Yours faithfully,

(Dr.Ashok Kumar)
Deputy Director General (M&E)

Copy for information and necessary action to:-

1) The Project Director, Maharashtra State AIDS Control Society, Ackworth Leprosy Hospital Campus, Behind SIWS Collete, R.A. Kidwai Marg, Wadala(West), Mumbai - 400031, with request to extend a support to the concerned student to undertake the study at ARTCs from Pune district
Chairman, Ethics Committee, B.L.D.E.U. Sri. B.M. Patil Medical College Bijapur- 03, with request to closely monitor the study with respect to adherence to Ethical standards.

2) DDG (CST)/NACO/GOI

ANNEXURE IV

PERMISSION LETTER FROM MSACS

Maharashtra State AIDS Control Society
Government Of Maharashtra

MSACS

RA Kidwai Marg, Near Wadala OverBridge,
Wadala (West), **Mumbai-400031**

MSACS/CST/research/2015 |10223-28
Date: 29th May 2015

To,

Dr. R. N. Hiremath,
C/O NS Hiremath,
Postal colony, Vidhyagiri,
Bagalkot – 587102,
Karnataka
Cell no. – 09801661831 (drshekar80@gmail.com)

Sub: PHD Research Project entitled 'A Prospective study to assess the factors
affecting nutritional status of people living with HIV/AIDS (PLHAs) receiving
Anti-Retroviral Threapy (ART)".

Ref. : 1) Letter of NACO T-11020/55/2013-NACO/-R&D dated 20th November 2014.

With reference to above NACO letter permission granted for undertaking the Ph. D
thesis study at ART centres from Pune district.

Your proposal has been be reviewed R & D CST division, NACO. Permission is hereby
accorded for undertaking this study subject to following conditions.

1. Copy of the modified proposal and institutional ethics committee clearance
   should be submitted to NACO/ MSACS before commencing the study.
2. Copy of the final report may be submitted to NACO & MSACS.
3. Any publication out of this study will need to have prior NACO approval.

Entire expenditure for this study will be born by the Ph.D. student Instute/Univercity
undertaking this research. No technical or financial support will be provided by
NACO/GOI/MSACS.

Any adverse events observed during this study may please be communicated to NACO.

Project Director
Maharashtra State AIDS Control Society
Mumbai

Copy to:

1. DPO, Pune
2. ARTC - BJMC, AFMC, YCM, NARI – Pune, Aundh CH, Yerwad Hospital, & Baramati.

art@mahasacs.org, jdcst@mahasacs.org, ccc@mahasacs.org
☎: 2411 3097, 2411 5619, 2411 5791   Fax: 24115825, **24113123**

Priti –Div. Asst. D:\Letter\2015 Letters Auto save.docx

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PAPER PRESENTATIONS

Paper presentations at National conferences

1. People Living With HIV/AIDS (PLHAs) Nutritional Status: Need To Re-Think And Measures To Be Taken For Improvement" was presented at IPHACON 2017, at Jodhpur from 24-26 Feb 2017.

2. "Nutritional status of people living with HIV/AIDS - Need for active interventions" was presented at 5th Annual conference of Clinical Infectious Diseases Society at New Delhi from 21st Aug – 23rd Aug 2015

ONLINE HIV MANAGEMENT COURSE FROM
JOHNS HOPKINS UNIVERSITY

Johns Hopkins University
and the
HIV Medicine Association of India

Certificate of Achievement

does hereby certify that

Ravishekar N. Hiremath

has completed to satisfaction

HIV MANAGEMENT COURSE
February - December 2014

The course is made possible with a scientific grant from Mylan

HIV Medicine Association of India

Board of Directors, HIV/MAI

Director, JHU CCGHE

PUBLICATIONS

1. Hiremath RN, Patil SS, Yadav AK. "Nutritional Status Of People Living With HIV/Acquired Immunodeficiency Syndrome - A Cross-Sectional Study". Asian J Pharm Clin Res, Vol 11, Issue 7, 2018, 456-459

2. Hiremath RN, Patil SS, Yadav AK, Kadam DB. Quality of Life and Nutritional Status of People Living with HIV/AIDS (PLHA's) in Western Maharashtra-A Prospective Cohort Study. Journal of Clinical and Diagnostic Research. 2019 Jun, Vol-13(6): LC01-LC06

3. Hiremath RN, Patil SS, Kadam DB. Food Insecurity, Standard of Living and Nutritional Status of People Living with HIV/AIDS (PLHAs) on ART: Rural–Urban Differences. Indian Journal of Public Health Research & Development. Jan2020, Vol. 11 Issue 1, p546-553