

## Socio-Demographic, Clinical Predictors and Economic Barriers of ART Adherence Among PLHIV of Western India - a cross-sectional study

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### ABSTRACT

**Background:** Anti-Retroviral Therapy (ART) drugs adherence is essential for achieving viral suppression, yet barriers persist affecting its adherence particularly in high migrant and overpopulation area of South Gujarat, India. **Aim:** To identify factors of poor ART adherence. **Methodology:** A cross-sectional study was conducted to identify the barriers of good ART adherence at ART Centre, Surat over 1 year; PLHIV (n=240) using pre- tested, semi-structured questionnaire. **Results:** Middle-aged: 36–55 yrs (56.25%), males (56.7%), illiterate (36.7%), interstate migrants (70%), poor social support (33.3%), non-disclosure of HIV status (10.4%), and side effects (16.25%) showed poor adherence, higher viral load, and low CD4 counts. Economic barriers: average loss of wages Rs. 455/- per visit and 45-60min travel time to visit ART centre. There was significant difference between mean  $\pm$  SD of CD4 count & duration of treatment ( $p=0.038$ ), adherence & side effects ( $p=0.003$ ), adherence & last viral load ( $p=0.001$ ). High viral load is associated with lower adherence ( $r= -0.319$ ,  $p=0.025$ ). Travel and social events, communication gaps, geographic inaccessibility, fear of discrimination, false sense of security, job insecurity decreases adherence. **Conclusion:** Causes of poor adherence are migration, economic loss, side effects and lack of social support. Interventions like single long-acting drug, multi month dispensing may help in improving adherence.

### KEYWORDS

ART, PLHIV, one shot solution, multi-month dispensing (MMD)

### INTRODUCTION

HIV/AIDS continues to be formidable global health challenge, with 40.8 million People Living with HIV (PLHIV) worldwide by the end of 2024(1)(2). During that, HIV/AIDS account for 6,30,000 people deaths and 1.3 million new HIV infection, comprising 1,20,000 children. (1) The efficacy of HIV management requires sustained adherence to antiretroviral therapy (ART) among PLHIV. (3) To address this need, the ART coverage expanded to 31.6 million people receiving treatment in 2024 (77%) from 30.3 million in 2023.(1)

Identifying the determinants of poor ART adherence among PLHIV is essential for improving treatment outcome. Despite its extensive research regarding, a gap has been remained in achieving optimum ART adherence in the Western India. In 2021, this area provided 1,13,532 (93,717- 1,38,484) PLHIV and is defined by its unique demographic and epidemiological profile.(4) Moreover, as Surat is rapidly developing city with 55% migrant population(5), the sociocultural dimensions affecting adherence may evolve over time necessitating localized and up-to-date research. Effectively suppressing the viral load to below 1000 copies/mL is a critical strategy for achieving the UNAIDS goal of 'End HIV' by 2030.

**Aim & Objective(s):** Objective: To determine the key factors of poor ART adherence by exploring challenges of sociocultural and medication related factors for poor adherence among PLHIV to achieve suppressed viral load as a policy for "Treatment as Prevention" strategy.

### MATERIAL & METHODS

It was a cross-sectional survey carried out in the Surat city of South Gujarat. The convenient sampling technique was used. As per the desk review conducted at ART Centre for available data till September 2023, the number of participants found with different ART adherence levels in a month were >95% adherence:  $\approx$  3000-3200 PLHIV; 80-95% adherence:  $\approx$  300 PLHIV; <80% adherence:  $\approx$  200 PLHIV and Lost to follow-up participants:  $\approx$  200. (Figure 1) The final sample size was 240, which was calculated using the formula  $n=z^2pq/L^2$  and taking prevalence rate of poor ART adherence 16.7%(3) with allowable error 5 and 10% for non-response rate and errors in data collection. As per National AIDS Control Organization (NACO), India, ART adherence <95% will be considered as "poor ART adherence".(6) As per NACO programmatic definition, 2024 "On ART Lost to Follow Up (LFU)" PLHIV is as follows: "PLHIV on-ART with no clinical contact or ARV pill pick-up for >28 days since last schedule/missed

appointment date.”(7–9) PLHIV with ART adherence of less than 95% consecutively over the last one month and provided informed written consent voluntarily were included in the study. The PLHIV <18 years or having severe cognitive impairments or who didn’t know the languages Hindi, Gujarati, or English were excluded from the study. (Figure 2)

The study was conducted from October 2023 to October 2024 (13 months). A semi-structured questionnaire was developed based on validated freely available scales (MMAS-8 (10) and OSSS-3(11)) and literature for data collection. A pilot study was conducted among 10 PLHIV then the proforma was finalized following peer review and expert opinion. The independent variables- socio-demographic factors were studied in relation to poor adherence. The face-to-face interviews of participants were conducted by the trained research personnel.

Data was entered in MS Excel and analysis was done in SPSS version 25. Chi-square test, t-test and Pearson correlation were used to identify associations between potential factors and poor ART adherence.

To maintain strict confidentiality, the participants’ data were anonymized, stored securely and made accessible only to authorized research personnel.

Ethics approval was granted by the Institutional Ethics Committee No. EC/NEW/INST/2021/2173 dated 01/03/2025 in addition to the permission from Gujarat State AIDS Control Society (GSACS). Prior to study inclusion, the informed consent was secured from all the participants. To maintain data integrity, the investigator supervised the data collection process on a daily basis to ensure both completeness and consistency.

**RESULTS**

The present study was conducted on 240 PLHIV with poor ART adherence rate. Out of 240 PLHIV with poor adherence, majority (55.83%, n=134) of the participants had adherence rate between 86-95%. Only 7 (2.9%) participants were found with adherence rate <50%, whereas 10 (4.16%) had restarted the treatment after a gap of few months of missed treatment.

Age and Gender: Majority (30%, n=72) of the participants belonged to 36–45 years followed by 46–55 years (26.25%, n=63). There was a predominance of male (n=136, 56.66%) and transgender were 3 (1.25%). The viral load >1 lakh was higher among males (3.67%, n=5) compared to females (2.97%, n=3).

Literacy: Illiterate were 88 (36.7%). Viral load >1 lakh was found in 2.27% (n=2) in illiterates PLHIV.

Migration: 168 (70%) PLHIV showed interstate migration. Out of them, 6 (3.57%) had adherence <50%, 5 (2.38%) had viral load >1 lakh, and 9 (5.35%) had CD4 count <100.

Marriage: Most of the PLHIV were married (59.58%, n=143), followed by single (17.91%, n=43), widow (16.25%, n=39) and divorced (6.25%, n=15). Married (3.49%, n=5) PLHIV showed higher viral load. However, 1 each from other categories of widow (2.56%), single (2.32) and divorced (6.66%) showed high viral load.

Poor social support was seen in 80 (33.3%) PLHIV. Out of them, 3 (3.75%) had adherence <50%, 5 (6.25%) had viral load >1 lakh, and 8 (3.33%) had CD4 <100.

Non-disclosure of HIV status: There were 25 (10.4%) PLHIV who did not disclose their HIV status to anyone. Amongst them, 2 (8%) had adherence <50%, 2 (8%) had viral load >1 lakh, 2 (8%) had CD4 count <100.

**Economic Barriers:**

Out-of-pocket expenditure: The average out-of-pocket expenditure was found to be Rs. 140 (range Rs. 20–500).

Wage loss: The average wage loss per day Rs. 455 (range ₹50–10,000). 157 (65.41%) PLHIV were working. Among them, 5 (3.18%) had adherence <50%, 6 (3.82%) had viral load >1 lakh, 10(4.16%) had CD4 <100.

Travel: The average travel time to reach ART centre ranged from 45–60 minutes per visit. Longer travel time (60 min) was observed in PLHIV with poor adherence and 45 minutes in both having higher viral load and low CD4 count.

**Clinical Outcome:**

Side effects were reported by 39 (16.25%) PLHIV, out of them, 3 (7.69%) PLHIV had poor adherence <50%, 3 (7.69%) PLHIV had higher viral load and 5 (12.82%) PLHIV had lower CD4 count.

Adherence Level: The average adherence range was 76–85%. The average adherence was found to be 82%. Majority (55.83%, n=134) had an adherence rate between 86-95%. Only 2.91% (n=7) had an adherence rate of <50%. However, viral suppression was poorer: average 68% adherence with viral load >1 lakh and 69% adherence with CD4 <100. 31 (12.91%) PLHIV on 2nd line ART. Out of them, 1 (3.22%) had adherence <50%, 3 (9.67%) had viral load >1 lakh, 2 (6.45%) had CD4 <100. The PLHIV on 3rd line regimen of ART drugs was observed in single (0.41%) participant who had low CD4 count of <100.

Last viral load count had a significant negative correlation with adherence rate (r = -0.319, p= 0.025), indicating that higher viral loads are associated with lower adherence.

Variables like age, MMAS score had weak, non-significant correlations with adherence. Additionally, wage or salary loss due to ART visits had a marginal negative correlation with adherence (r = -0.174, p = 0.057), suggesting economic challenges might slightly impact adherence, though not significantly. Other variables, such as total family income and travel time, showed negligible correlations with adherence.

**Table 1: Adherence rate, Last CD4 count and Last Viral load with various socioeconomic characteristics**

Socioeconomic characteristics	Category	Adherence rate (%) (Mean ± SD)	Last CD4 count (cells/μL) (Mean ± SD)	Last viral load count (copies/mL) (Mean ± SD)
Age group (years)	18-25	78.5 ± 18.9	808.53 ± 538.1	33174.83 ±166457.4
	26-35	84.51 ± 8.9	531.01 ± 335.9	2667.04 ±10490.5
	36-45	80.97 ±14.3	469.81 ± 261.2	15.918 ± 56605.8
	46-55	81.88 ± 11.4	435.57 ± 185.1	29949.17 ±178846.6
	56-65	82.13 ± 10.9	428.58 ± 190.1	19.125 ± 52.3
	>65	91.71 ± 2.0	618.28 ± 204.7	0

Socioeconomic characteristics	Category	Adherence rate (%) (Mean ± SD)	Last CD4 count (cells/μL) (Mean ± SD)	Last viral load count (copies/mL) (Mean ± SD)
Gender	F value/p value (ANOVA)	1.714 (0.131)	7.1633 (0.0000029) *	0.8043 (0.5475)
	Female	79.9 ± 16.4	608.7 ± 315.1	27352.5 ± 166056.2
	Male	77.7 ± 23.7	450.7 ± 317.4	9798.6 ± 44526.6
	Transgender	78.0 ± 12.5	481.3 ± 316.3	90.7 ± 157.0
	Total	78.6 ± 20.8	517.6 ± 324.6	17064.5 ± 112852.9
Marital Status	F value/p value (ANOVA)	1.198 (0.303)	7.050 (0.001) *	0.7120 (0.4916)
	Divorced/ Separated	84.2 ± 11.1	392.1 ± 211.1	16952.4 ± 46349.3
	Married	79.3 ± 21.0	511.7 ± 277.5	9083.5 ± 43308.7
	Single	76.1 ± 23.9	642.7 ± 496.6	26441.2 ± 139285.0
	Widow/Widower	76.7 ± 19.5	449.4 ± 238.7	36032.8 ± 223942.1
Literacy status	p-value (ANOVA)	0.723 (0.539)	3.579 (<0.015)*	0.702 (0.552)
	Illiterate	81.75 ± 12.2	462.01 ± 270.4	21257.43 ± 154579.6
	Literate	82.171 ± 13.6	549.756 ± 348.9	15540.766 ± 85161.9
Social Support	F value/p value (ANOVA)	0.05763 (0.81)	4.126 (0.0433)*	0.1365 (0.712)
	Poor	76.2 ± 22.6	410.9 ± 274.7	24153.1 ± 110524.8
	Moderate	81.0 ± 18.0	581.9 ± 369.8	5888.3 ± 34676.1
	Strong	76.6 ± 24.0	541.9 ± 219.5	33640.6 ± 210753.5
	p-value	0.222	0.001*	0.302

Table 2: Association of Adherence rate and Treatment variables among study participants (n= 240)

Treatment variables	Adherence rate n (%)						Chi-square	p-value	
	<50	51-75	76-85	86-95	Restart	Total			
Treatment regimen	First line (none/green)	6 (2.9%)	38 (18.3%)	38 (18.3%)	117 (56.3%)	9 (4.3%)	208 (86.7%)	14.1, df=8	0.079
	Second line (Red)	1 (3.2%)	7 (22.6%)	6 (19.4%)	16 (51.6%)	1 (3.2%)	31 (12.9%)		
	Third Line (Black)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	1 (0.4%)		
Duration of treatment in months	≤12 months	1 (4.8%)	8 (38.1%)	3 (14.3%)	8 (38.1%)	1 (4.8%)	21 (8.8%)	10.6, df= 12	0.561
	12-24 months	2 (12.5%)	2 (12.5%)	1 (6.3%)	11 (68.8%)	0 (0.0%)	16 (6.7%)		
	25-60 months	1 (2.8%)	3 (8.3%)	7 (19.4%)	24 (66.7%)	1 (2.8%)	36 (15.0%)		
	≥5 years	3 (1.8%)	32 (19.2%)	33 (19.8%)	91 (54.5%)	8 (4.8%)	167 (69.6%)		
Side effects	Absent	4 (2.0%)	36 (17.9%)	37 (18.4%)	118 (58.7%)	6 (3.0%)	201 (83.8%)	10.1, (4)	0.039*
	Present	3 (7.7%)	9 (23.1%)	7 (17.9%)	16 (41.0%)	4 (10.3%)	39 (16.3%)		

Table 3: Mean adherence rates, last CD4 count, and last viral load count based on treatment characteristics (n= 240)

Category	Adherence Rate (Mean ± SD)	Last CD4 Count (Mean ± SD)	Last Viral Load Count (Mean ± SD)	
Treatment Regimen	First line	82.46 ± 12.2	531.07 ± 336.0	71138.7 ± 238967.1
	Second line	78.87 ± 17.6	441.65 ± 215.6	106200.1 ± 243799.8
	Third Line	89.00 ± .	67.00 ± .	47687.0 ± .
	p-value	0.325	0.137	0.890
Duration on treatment	≤12 months	78.0 ± 16.2	331.5 ± 253.8	46997.0 ± 66395.9
	12-24 months	79.3 ± 21.7	603.1 ± 537.2	11243.8 ± 24760.7
	25-60 months	85.2 ± 9.1	518.4 ± 296.7	43214.6 ± 104576.5
	≥5 years	82.1 ± 12.2	532.6 ± 306.5	98453.2 ± 272054.9
Side Effects	p value	0.202	0.038*	0.844
	Absent	83.1 ± 11.2	523.5 ± 331.1	33364.3 ± 68474.1
	Present	76.0 ± 19.7	486.9 ± 290.9	332602.0 ± 532374.3
	p-value	0.003*	0.520	0.001*

Table 4: Reasons for poor ART adherence (Multiple answers)

Reason for poor ART adherence	Category	Frequency
Non-disclosure of HIV status		4
Social visit	Out of station / Travel	73

Reason for poor ART adherence	Category	Frequency
<b>Family/ Social system support</b>	Attending family function/ festival	74
	Death in family	9
	Emergency/ Sudden travel	7
	Family problem (HIV related)	1
	Dependence on husband/ family denial/ None to accompany to hospital	3
<b>Personal health status</b>	Health issue in family	2
	Own health issue and uneasiness	20
	Road Traffic Accident	3
<b>Work place issues</b>	Pill burden	1
	Leave not granted	14
	Wage loss	10
<b>Environmental</b>	Job insecurity	15
	Rain	16
<b>Travel</b>	Long distance and expenses	14
	Hurdles	16
<b>Previous leftover pills</b>		32
<b>Personal</b>	Forgotten	13
	No felt need of medication	7
	Relocation	3
	Skipped due to fasting	1
	Medicine stock out	2
	Time constraints (hospital)	1
	Delay in transfer	1
	Lost green book	1
	Believe in faith healers	1
	<b>Financial constraints</b>	
<b>No reason given</b>		8

## DISCUSSION

To achieve the goal 'End- AIDS epidemic' by 2030, the WHO advocated 'Test & Treat Policy' as a crucial strategy. In India, NACO implemented this policy with integrated framework of HIV programme—universal "test-and-treat," routine viral-load monitoring, and the Undetectable = Untransmittable (U=U) concept. By providing free access to effective ART through established ART centres under public health system, this programme showed successful transition from a life-threatening HIV/ AIDS condition into a chronic, manageable disease for PLHIV. (12,13)

Despite this strong, supportive policy with enabling environment and the wide availability of free treatment, poor ART adherence still persists, jeopardizing effective viral suppression and increasing the risk of treatment failure and drug resistance.

In this study, the mean age was  $40.49 \pm 28.99$  years. Comparable age structures were noted by Basu *et al.* ( $36.9 \pm 10.84$  years). There is also a preponderance of males (0.22%; Range: 0.18- 0.27%) in the annual report of 2024-2025.(7) (14) NACO shows male preponderance of 22,37,308 (Range: 17,73,563-28,69,016) which is 0.23% (0.18 -0.34). (15)

In this study, poor ART adherence is observed in the lower age group, married and economically disadvantaged participants which is also seen in a study by Basti, *et al.*(16). According to policy 'Test and Treat', ART is initiated immediately following diagnosis. This often resulted in poor adherence due to false sense of security and absence of clinical features, psychological burden of stigma and discrimination alongside pill burden.

**Disclosure of HIV status** to whom shows a statistically significant difference with the adherence rate. It means it is a significant factor in adherence rate ( $\chi^2=48.9$ ,  $p<0.001$ ). **PLHIV who disclosed their HIV status to a spouse & other family members showed better adherence compared to PLHIV who disclosed to spouse & workplace. This emphasizes the importance of social support system in achieving good adherence and suppress viral load.** In this study, 44.2% disclosed their HIV status to other family members. 85.7% disclosed their HIV status to all the family members. (17) Disclosure of HIV status plays pivotal role in improving adherence. (17)(18) Disclosure of HIV status is one of the factors for better adherence, which if not done is the root of stigma and fear of discrimination referring to abusive behaviour and may affect mental health of PLHIV. (17)(18) **Just a single PLHIV has disclosed HIV status at workplace highlights the persistent prevalence of stigma and discrimination. This necessitates rigorous implementation of HIV/AIDS Prevention Act 2017, Govt. of India for greater integration and involvement of PLHIV in the community.**(17) In the present study, the occurrence of a side effects was statistically significant associated with adherence rate and last viral load. Similarly, a study from South India reported 37.5% PLHIV had side effects achieved adherence rate of  $\geq 95\%$ , compared to 76.2% PLHIV without side effects. (19) This study demonstrates that out of 208 PLHIV who were on first line treatment regimen already had low adherence, were changed to a 2nd line drug regimen and subsequently to 3rd line regime. This clearly specifies that treatment failure is the root cause of regimen escalation. First line ART failure is reflected due to poor ART adherence, similar behaviour continues and is again

reflected in second line failure. If this reason behind poor ART adherence will not intervene timely, then this may face the crisis of third line failure and ultimately leads to devastation of program. (20)

**Immunological parameters** are also lower due to less adherence. Immunological parameters failed in 10.6% of the participants(14) CD4 count for PLHIV on treatment duration of >5years was increased to  $532.6 \pm 306.5$ ,  $p=0.038$  which was statistically significant. Likewise, an Indian study showed CD4 count of  $545.23 \pm 259.11$  cells/mm<sup>3</sup>,  $p=0.000$  after treatment compared to pre-ART CD4 count which was  $171.32 \pm 65.23$  cells/mm<sup>3</sup>.(21) This suggests immunological improvement due to ART drugs. In this study, high viremia was observed with poor ART adherence while a study carried out in Pune showed 13% virological failure rate. Lower adherence rate has been identified as the major factor of virological failure.(22) It is an obstacle in HIV prevention programme strategy of treatment as prevention.

A statistically significant difference was observed in mean of CD4 count with gender, marital status, literacy status and social support. Women have higher mean of CD4 count  $\sim 995 \pm 335$  cells/ $\mu$ L compared to males  $\sim 852 \pm 273$ .(23) The absolute CD4 + T cell counts in female were significantly high.

Marriage couldn't be an independent predictor of CD4 count, but it might have a positive impact on health via social support and health behaviour. A sero-positive couple- both are taking care of each other by keeping reminders in cell phone for precision of ART drug regularly, so couple counselling is an important factor for motivation. During couple counselling, emphasis on U=U will encourage them for safer sex practices in sero-concordant/ sero-discordant couple.(24)

Social support is the potential factor for psychosocial intervention alongwith ART drugs.

A significant negative correlation was observed between last viral load count and adherence rate ( $r = -0.319$ ,  $p = 0.025$ ). Similarly, a negative correlation was observed between viral load and ART adherence rate which was  $-0.7688$ ,  $p < 0.05$ ), indicates poor adherence rate increases viral load.(25)

The present study outlines out station/travel, family function, ill health and, transport (travel cost, travel time), accessibility and sociocultural reasons were the determinants of poor ART adherence. Another study of India emphasized financial constraints for travel, attending family function, fears of discrimination and rude behaviour of ART staff with patients were the key determinants of poor ART adherence.(26)

**Health System strengthening:** PLHIV face the issues of transport to ART centre. Therefore, it would be good if a 3 months medicine is given together provided PLHIV take it in an appropriate manner. Also, a single shot of long acting medicines would help. Despite ART being available to the patients free of cost, the loss of wage becomes a substantial financial burden making it a key barrier for poor ART adherence.(27) Implementing multi-month dispensing ARV drugs to the asymptomatic and patients having good adherence, as recommended by WHO 'Service Delivery for the treatment and care of PLHIV-April 2021' will address the major determinants of

poor adherence such as long-distance travel time/ out station visit/ family visit (social gathering), wage loss.(28)

#### CONCLUSION

To achieve the goal of 'End HIV' by 2030, interventions must address the specific barriers identified in the study that included economic loss, migration, and side effects.

#### RECOMMENDATION

A single long-acting shot of ARV can resolve most of the problems of side effects and travel. Mainstreaming of HIV program is essential; health staff should ensure that PLHIVs admitted for other medical issues receive their ART on time and also to improve interdepartmental coordination. When the PLHIVs are admitted to tertiary care hospital, deputation of resident doctors from Medicine, Paediatrics, TB-Chest physician, Obs. & Gyn., Skin and VD, Psychiatry, and Community Medicine for hands-on training at ART centre to reduce workload and quality management. Clinical care should emphasize on focused counselling sessions to cope with challenges and side-effect of ARV reporting management to preparing PLHIV for initiation of ART and when to return. Additionally, PLHIV should be supported with financial help to compensate loss of wages.

#### LIMITATION OF THE STUDY

NACO's pill counting method to assess ART adherence introduces recall bias and overreported adherence. This approach claims false good adherence to evade calls/reminders from ART centre, which they often associate with stigma and discrimination.

#### RELEVANCE OF THE STUDY

As per WHO – UNAIDS guidelines, 'Treatment as Prevention' policy, suppressed viral load is very vital for U=U. For maintaining suppressed viral load, adherence is a key factor. This study has identified the barriers of poor adherence.

#### AUTHORS CONTRIBUTION

All authors have contributed equally.

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Nil

#### CONFLICT OF INTEREST

There are no conflicts of interest.

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#### DECLARATION OF GENERATIVE AI AND AI ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

The authors haven't used any generative AI/AI assisted technologies in the writing process.

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