# World Health Organization Dimensions of Adherence to Antiretroviral Therapy: A Study at Antiretroviral Therapy Centre, Aligarh

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## Abstract

**Introduction:** With the availability of antiretroviral therapy (ART) and subsequent change in the HIV/AIDS disease dynamic to a chronic manageable disease, adherence studies have received increasing attention. However, there is a paucity of studies that have considered World Health Organization (WHO) dimensions of adherence to ART. Therefore, this study was conducted with the objectives of determining the prevalence of adherence and the association of various factors across five WHO dimensions to adherence. **Methods:** A cross-sectional study was carried out at the ART Centre, Aligarh. A total of 440 adult patients, taking treatment from the ART Centre, Aligarh were selected. A self-reported instrument of missing pills was used to measure adherence. Various factors across five WHO dimensions were studied. **Results:** Prevalence of adherence in our study was 81.3%. Among the five dimensions of adherence, distance from home (odds ratio [OR] 0.980; 95% confidence interval [CI] 0.964–0.997) among socioeconomic determinants, frequent adherence counseling (OR 8.737; 95% CI 1.473–7.365) among therapy related, drug regimen (OR 2.202; 95% CI 1.023–4.738) and absence of side effects (OR 3.293; 95% CI 1.473–7.365) among therapy related, absence of substance abuse (OR 2.747; 95% CI 1.209–6.243), and perceived change in health status (OR 4.196; 95% CI 1.613–10.915) among patient-related dimension were found to be significantly associated with adherence to ART, while clinical condition dimension did not play a significant role. **Conclusion:** The ART adherence rate is still below satisfactory levels for long-term viral load suppression. WHO multidimensional approach – which was found to be quite relevant in our study setting – could be applied to effectively solve the adherence problem in our country.

Keywords: Adherence, antiretroviral therapy, HIV, patient compliance

## **INTRODUCTION**

The Joint United Nations Programme on HIV and AIDS (UNAIDS) aim of "Ending the AIDS" epidemic by 2030 cannot be accomplished without the due care, support, and treatment of 2.12 million people living with HIV (PLHA) in India.<sup>[1]</sup> With new infection falling to half since 2001, India's progress in curbing the epidemic is laudable, especially when compared to neighboring countries like Pakistan, where it grew eightfold during the same time period.<sup>[1,2]</sup> Establishment of antiretroviral therapy (ART) Centre as a service delivery point providing free ART, played a pivotal role in controlling the deadly infection and reducing it to a chronic manageable disease. To obtain maximum benefits, as with other chronic diseases, a good compliance in the form of optimal adherence (at least 95%) has to be maintained.<sup>[3,4]</sup>

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The consequences of poor adherence to treatment often leads to poor health outcomes and increased healthcare costs and also contributes to antimicrobial resistance.<sup>[3]</sup>

Contrary to popular perception that patients are the main source of the "problem of compliance," the current understanding acknowledges that a systems' approach is needed to understand the phenomenon. The World Health Organization (WHO) has made a significant contribution to the understanding of

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How to cite this article: Alvi Y, Khalique N, Ahmad A, Khan HS, Faizi N. World Health Organization dimensions of adherence to antiretroviral therapy: A study at antiretroviral therapy centre, Aligarh. Indian J Community Med 2019;44:118-24. Received: 03-06-18, Accepted: 05-03-19 adherence by asserting adherence as a multidimensional phenomenon governed by the interplay of five sets of factors, also known as "dimensions."[3] These five dimensions include socioeconomic factors, patient-related factors, clinical condition-related factors, therapy-related factors, and healthcare system-related factors [Figure 1]. Across these dimensions, there are multiple factors which may vary among different populations/settings and could be used to design specific policies that can improve adherence in the national and local context.<sup>[3]</sup> Despite the advantages of these dimensions in terms of its systematic approach, to the best of our knowledge, there has not been a substantial study that has attempted to measure them from India and other developing countries. Therefore, this study was conducted with two objectives: (1) To determine the prevalence of adherence among ART patients and (2) To find the association of various factors across the five WHO dimensions affecting adherence.

# **Methods**

## Study setting and population

This was a cross-sectional study, conducted over a period of 12 months, from July 2015 to June 2016. All adult (>18 years) HIV/AIDS-infected patients, taking ART from ART centre, Jawaharlal Nehru Medical College, Aligarh, were eligible for the study. The exclusion criteria were (1) patients who have taken ART for <6 months, (2) patients on  $2^{nd}$  line ART, (3) patients suffering from any acute medical condition during the study, and (4) any psychiatric condition owing to which a patient could not give valid consent.

### Sampling

The sample size was calculated using the formula,  $n = 4p (1-p)/d^2$ , where p stood as the prevalence and d as the



Figure 1: Five dimensions of adherence to antiretroviral therapy

absolute precision (taken as 10%). Based on WHO rigorous reviews, which found adherence to average at 50%,<sup>[3]</sup> the sample size came out to be 400. However, presuming a nonresponse rate of 10%, we planned to recruit 440 patients. Preparing the sampling frame from the list of the patients reporting to ART centre on the day of data collection (done thrice a week), we performed systematic random sampling for selecting the sample population. After taking into account the daily average attendances at ART centre, the sampling interval was calculated to be 10. The first number was chosen randomly, after which every tenth patient in the sampling frame was selected for data collection. If the selected patient was not eligible for this study or had been interviewed earlier, the next patient from the sampling frame was taken for the interview without disturbing the list of patients.

### **Study instruments**

The data were collected by face-to-face interview using a predesigned and pretested questionnaire administered in local language. All the interviews were conducted by same interviewer. The determinants of adherence were analyzed across the five dimensions of adherence as given by WHO, adapted with minor modifications [Figure 1]. For measuring adherence, we used a self-reported instrument of missing pills, modified from Adult AIDS Control Trial Group questionnaire to assess adherence over the last 30 days.<sup>[5]</sup> Self-report tools have been extensively used internationally as well as in the Indian setup in the past.<sup>[6-10]</sup> The data we obtained through self-reporting were further verified by pill-count, to increase the accuracy of the assessment. Patients were considered "Adherent" if they reported to have taken 95% or more of prescribed pills, while those who reported taking <95% of prescribed pills were labeled as "nonadherent" in accordance with National AIDS Control Organization (NACO) guidelines.<sup>[4]</sup> Depression was measured by the Hindi version of Patient Health Questionnaire-9 which has been validated for Indian settings.<sup>[11]</sup> Socioeconomic status was measured by Modified B G Prasad's classification.<sup>[12]</sup>

#### Statistics analysis

The data were entered and analyzed in IBM SPSS version 20 (SPSS Inc., Armonk, NY).<sup>[13]</sup> The categorical variables and proportions were represented by a percentage (%) along with 95% confidence interval (CI) that was calculated by Agresti-Coull methord.<sup>[14]</sup> Association between various factors and adherence was done by logistic regression, and all those variables which were significant were further analyzed using multiple logistic regression, through "enter" method. Probability (p) was kept at 5% level of significance.

### Ethics

As the study involved HIV/AIDS patients, utmost importance was given to ethics. Before its commencement, the study was approved by Institutional Ethics and Research Advisory Committee, JN Medical College, AMU, Aligarh. An informed written consent was taken from each selected participant to confirm willingness. The actual study was preceded by an individual rapport building session, where the purpose of the study and its implications were explained. The participants were assured about their privacy and confidentiality. Appropriate health education, adequate counseling, and referral, whenever needed, were provided to all the patients after the interview.

# RESULTS

During the study period, 440 patients were enrolled. Out of them, six patients were unable to complete the interview; therefore, 434 patients were analyzed finally. Reasons for nonparticipation were withdrawal of consent before completing the interview (n = 3), citing time constraints (n = 2), and noncooperation (n = 1).

## Sociodemographic and clinical characteristics

A total of 434 patients (262 males, 170 females, and 2 transgenders) were interviewed during the study period. The mean age of the sampled population was  $39.02 \pm 9.82$  years. Majority of them were married (65.4%), of a nuclear family (62.7%), Hindu (88.9%) by religion, and lived in a rural area (73.7%). Only 67.8% patients were literate, whereas only 66.8% of the study population were employed. About two-third belonged to lower socioeconomic Class (IV and V, Mod. BG Prasad). Majority of the participants were asymptomatic (Stage I WHO staging) with a mean CD4 cell count of  $384.57 \pm 179.54$ cu. mm. In the previous 30 days, 81 (18.7%) patients gave history of substance abuse and 70 (16.1%) patients suffered from depression. Most of the participants were taking a fixed-dose combination either of Tenofovir, Lamivudine, and Efavirenz (50.9%) or Zidovudine, Lamivudine, and Efavirenz (45.2%). Side effects from antiretrovirals were reported by 18.7% of the participants during previous 30 days. The majority (388/434) of the patients perceived benefit from the ART.

### Adherence to antiretroviral therapy

The prevalence of adherence to ART among the study participants during the last 30 days was found to be 81.3% (353/434) (95% CI 77.4–84.7). Among nonadherents (81/434), the majority (72.8%) had missed only a few pills, while 5.1% reported having taken less than half of their prescribed drug [Table 1].

Table 1	Distrib	ution o	f patients	attending	antiretroviral
therapy	center	on the	basis of	pattern of	adherence

Pattern of adherence	Frequency (%)
Adherent (%)	353 (81.3)
100	300 (69.1)
95-99	53 (12.2)
Nonadherent (%)	81 (18.7)
80-94	59 (13.6)
50-79	18 (4.1)
<50	4 (0.9)
Total	434 (100)

### Five dimensions of adherence

To study the factors associated with adherence to ART, first, an unadjusted odds ratio (OR) for selected socioeconomic, patients' related, clinical condition-related, therapy related and healthcare system-related factors [Figure 1] were calculated. In univariate analysis, the adherence to ART was significantly associated with factors across all the five WHO dimensions of adherence as shown in Table 2.

All the factors that were significant in univariate analysis were further analyzed by multiple logistic regression. Distance from home (OR 0.980; 95% CI 0.964–0.997) among socioeconomic dimension; frequent adherence counseling (OR 8.737; 95% CI 4.076–18.727) among health system-related; non-Efavirenz-based drug regimen (OR 2.202; 95% CI 1.023–4.738) and absence of side effects (OR 3.293; 95% CI 1.473–7.365) among therapy related; and absence of substance abuse (OR 2.747; 95% CI 1.209–6.243) and perceived change in health status (OR 4.196; 95% CI 1.613–10.915) among patient-related dimension were found to be significantly associated with adherence to ART [Table 3].

# DISCUSSION

The purpose of the study was to determine the prevalence of adherence to ART and factors affecting it across the five dimensions. The prevalence of adherence to ART in our study population was found to be 81.3%. Among the five dimensions of adherence, we found socioeconomic, health system-related, therapy-related, and patient-related dimensions to be significantly affecting adherence, while clinical condition dimension was found to play less of a role.

As far as the prevalence of adherence to ART is concerned, a similar prevalence was reported in Central India (89.1%) and West Bengal (87%).<sup>[6,15]</sup> A multicentric study among the Indian population found a pooled adherence of 75.5%.<sup>[16]</sup> Studies from other part of Asia also reported similar findings.<sup>[17,18]</sup> Although most of these studies are in line with our study findings, some Indian studies have also reported higher rates of adherence, ranging from 90% to 93%.<sup>[9,19]</sup> Further comparison with these studies is difficult due to the differences in instruments used for assessing adherence, together with other methodological, settings-related, and clinical differences.

Among the socioeconomic dimension of adherence, we found the greater the distance patients have to travel, the higher the chance for nonadherence to the treatment. The association of distance to ART centre and adherence has been documented from different parts of the world<sup>[20-22]</sup> although some studies failed to demonstrate this association.<sup>[15,18,23]</sup> Apart from the distance, none of socioeconomic factors were found to be significantly associated – which is in concordance with the various studies done in India, as most of these studies were done in similar centers getting free ART from NACO.<sup>[8,15,23,24]</sup> Among the therapy-related dimension, we found nonadherence to be significantly associated with (a) Drug-related side effect and (b) Efavirenz-combined therapy. This supports the findings

Table 2: Univariate analysis of various factors among five dimensions affecting adherence to antiretroviral therapy				etroviral therapy
Dimension	Variables	Frequency (%)/mean±SD		Unadjusted OR
		Non-Adherent	Adherent	
I. Socio-economic dimension	Age	37.00±8.56	39.49±10.04	1.028 (1.001 - 1.055)
	Sex			
	Male	45 (17.2%)	217 (82.8%)	1.206 (0.735 - 1.976)
	Transgender	2 (100%)	0 (0%)	0
	Female	34 (20.0%)	136 (80.0%)	Reference
	Martial Status			
	Married	49 (17.3%)	235 (82.7%)	1.301 (0.791 - 2.139)
	Not married	32 (21.3%)	118 (78.7%)	Reference
	Literacy			
	Literate	54 (18.4%)	240 (81.6%)	Reference
	Illiterate	27 (19.3%)	113 (80.7%)	1.062 (0.636 - 1.774)
	Socioeconomic status*			
	I, II, II	27 (19.7%)	110 (80.3%)	Reference
	IV &V	54 (18.2%)	243 (81.8%)	1.053 (0.661 - 1.847)
	Family support			
	Satisfied	64 (17.2%)	308 (82.8%)	1.818 (0.978 - 3.378)
	Dissatisfied	17 (27.4%)	45 (72.6%)	
	Social Support			
	Present	10 (9.7%)	93 (90.3%)	2.540 (1.257 - 5.130)
	Absent	71 (21.5%)	260 (78.5%)	Reference
	Distance	65.67±58.83	44.81±33.64	0.989 (0.984 - 0.995)
	Cost	150.73±124.87	124.865±76.96	0.996 (0.994 - 0.999)
II. Healthcare system dimension	Waiting time			
-	<30 min	22 (12.5%)	154 (87.5%)	2.075 (1.218 - 3.536)
	30 min or more	59 (22.9%)	199 (77.1%)	Reference
	Last counseling			
	last month	17 (6.3%)	253 (93.7%)	9.170 (5.106 - 16.470)
	> 1 month	61 (38.1%)	99 (61.9%)	Reference
	Services satisfaction	· · · ·	. ,	
	Satisfied	69 (17.2%)	332 (82.8%)	2.749 (1.292 - 5.851)
	Dissatisfied	12 (36.4%)	21 (63.6%)	
III. Therapy related dimension	Regimen		× /	
	TLE & ZLE	57 (24.1%)	180 (75.9%)	Reference
	ZLN and others	24 (12.1%)	173 (87.8%)	2.283 (1.356 - 3.842)
	Side effects		· · · ·	
	Yes	28 (34.6%)	53 (65.4%)	Reference
	No	53 (15.0%)	300 (85.0%)	2.990 (1.737 - 5.147)
	Time since treatment			
	< 5 years	64 (19.9%)	257 (80.1%)	Reference
	> 5 years	17 (15.0%)	96 (85.0%)	1.406 (0.784 - 2.522)
IV. Condition related factor dimension	WHO staging (current)			
	I (Asymptomatic)	40 (16.1%)	209 (83.9%)	1.488 (0.916 - 2.415)
	II, III & IV	41 (22.2%)	144 (77.8%)	Reference
	CD4 cells (current)	368.76±186.00	388.25±178.09	1.001 (0.999 - 1.002)
	CD4 cells (progression)	148.54±160.58	192.84±168.65	1.002 (1.000 - 1.003)
	Depression			
	Present	19 (27.1%)	51 (72.9%)	Reference
	Absent	62 (17.0%)	302 (83.0%)	1.815 (1.002 - 3.285)

Contd...

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Table 2: Contd				
Dimension	Variables	Frequency (%)/mean±SD		Unadjusted OR
		Non-Adherent	Adherent	
V. Patient related factor dimension	Substance abuse			
	No	59 (16.7%)	294 (83.3%)	1.858 (1.057 - 3.265)
	Yes	22 (27.2%)	59 (72.8%)	Reference
	Perceived change			
	Improved	61 (15.7%)	327 (84.3%)	4.124 (2.166 - 7.850)
	Not improved	20 (43.5%)	26 (56.5%)	Reference
	Knowledge about ART			
	Yes	5 (8.9%)	51 (91.1%)	Reference
	No	76 (20.1%)	302 (79.9%)	2.567 (0.990 - 6.653)
	HIV status discloser			
	Yes	65 (18.1%)	295 (81.9%)	1.252 (0.677 - 2.316)
	No	16 (21.6%)	58 (78.4%)	Reference
	Felt Stigma			
	Yes	22 (30.6%)	50 (69.4%)	Reference
	No	43 (14.9%)	245 (85.1)	2.507 (1.380 - 4.555)

\*Few variables across the five dimension such as employment and economic dependency were analyzed but not showed in final univariate analysis [Table 2] as they were either highly correlated with other independent variables and/or were not significantly associated with dependent variable, thus omitted from final tabulation to make the result brief and clear. \*SD: Standard deviation, TLE: Tenofovir, Lamivudine and Efavirenz, OR: Odds ratio, ZLN: Zidovudine, Lamivudine and Nevirapine, ZLE: Zidovudine, Lamivudine, and Efavirenz

of previous studies.<sup>[16,21,25,26]</sup> The side effects to drug are known and proven determinant of adherence to chronic therapy.<sup>[3]</sup> The patients taking Efavirenz-combined therapy were twice more nonadherent to their treatment as compared to those who were taking other drug combinations. This could be due to the Efavirenz-associated side effects, although the association of adherence and Efavirenz was significant even after adjusting for side effects. Therefore, a regular screening and management of side effects is vital to ensure good compliance.

Counseling of patients emphasizing on adherence was the strongest determinant of adherence, which was the part of health system-related dimension. Apart from history of ever being counseled, months since the last counseling session attended was also significantly associated with adherence to ART. The importance of a regular counseling has been stressed by many researchers as this established trust, boosts confidence, motivates the patients, and strengthens the patientprovider relationship.<sup>[8,15,16]</sup> In addition, regular counceling session also provides an opportunity to screen and manage side effect of drugs - another significant factor associated with adherence in our study. Therefore, we believe that a strong, effective, and regular counseling of ART patients could significantly improve the adherence of ART, as others have also suggested.<sup>[27]</sup> Among the patient-related factors dimension, we found that those patients who gave the history of substance abuse in last 6 months had about three times higher chances of nonadherence to ART. Substance abuse has been labeled as one of the stronger predictors of nonadherence to ART by WHO and others.<sup>[3,28]</sup> The patients who reported to have any perceived benefit from ART were about four times likely to be adherent to ART as compared to those who did not, replicating the findings of previous studies from India and internationally, though studies in eastern part of India by Saha et al., had

differing results.<sup>[6,15,27,29]</sup> However, Saha *et al.*, measured adherence by different instrument – which has been questioned for overestimation of adherence.<sup>[6]</sup> We did not find any of the clinical condition-related factors having a significant effect on adherence. Varied results have been documented, with some demonstrating a significant effect of lower CD4 levels and presence of depression on adherence;<sup>[7,9,10,15]</sup> others failed to show any relationship between disease characteristics and symptomatology with adherence.<sup>[21,30]</sup>

### Limitations

Our study also had a few limitations. First, it was a cross-sectional study done in a hospital setting, restricting its generality, though most of the patients of HIV/AIDS in India avail treatment from these ART centers only. Second, we refrain from making any causal claims because of the study design, as the temporality cannot be ascertained. Third, selection bias may have occurred as we interviewed only the patients who reported to ART centre. Furthermore, by excluding patients who have taken <6 months of treatment, we may exclude a lot of patients, although they are unlikely to be a chronically managed patient, in which WHO dimensions of adherence are applicable.

## CONCLUSION

We conclude that adherence to ART in a low-middle income country like India is still below than the satisfactory levels for long-term viral load suppression. We also conclude that the WHO multidimensional approach to study adherence is especially relevant to developing countries, with significant relationship between adherence and many of these factors. Finally, given the importance of counselling, increasing its frequency and incorporating it with screening for side-effects, adherence for ART can be improved.

## Table 3: Multivariate analysis of various factors among five dimensions affecting adherence to antiretroviral therapy

Dimension	Variables	Adjusted OR	
I. Socio-economic	Age	1.026 (0.987 - 1.067)	
dimension	Social Support		
	Present	1.699 (0.688- 4.193)	
	Absent	Reference	
	Distance	0.980 (0.963 - 0.997)	
	Cost	1.007 (0.999 - 1.016)	
II. Healthcare system	Waiting time		
dimension	<30 min	Reference	
	30 min or more	1.292 (0.608 - 2.743)	
	Last counseling		
	last month	8.505 (3.975-18.196)	
	> 1 month	Reference	
	Services satisfaction		
	Satisfied	2.036 (0.606 - 6.837)	
	Dissatisfied	Reference	
III. Therapy related	Regimen		
dimension	TLE & ZLE	Reference	
	ZLN and others	2.202 (1.023 - 4.738)	
	Side effects		
	Yes	Reference	
	No	3.293 (1.473 - 7.365)	
IV. Condition related	CD4 cells progression	1.002 (0.999 - 1.004)	
factor dimension	Depression		
	Present	1.470 (0.593 - 3.647)	
	Absent	Reference	
V. Patient related	Substance abuse		
factor dimension	No	2.769 (1.216 - 6.306)	
	Yes	Reference	
	Perceived change		
	Improved	3.813 (1.435 -10.132)	
	Not improved	Reference	
	Felt Stigma		
	Yes	Reference	
	No	2.192 (0.931 - 5.160)	

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## **Conflicts of interest**

There are no conflicts of interest.

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