# **Original Research Article**

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# Factors associated with anti-retroviral therapy adherence among people living with HIV visiting IRT Perundurai medical college hospital link ART centre, Perundurai, Tamilnadu, India

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### **ABSTRACT**

**Background:** National AIDS control organisation aims to provide wholesome management to PLHIV. This is ensured by universal access to free and comprehensive care, support and treatment in health delivery facilities across the country by dynamic linkages and referral mechanism for monitoring, mentoring, decentralization and specialized care and treatment. Objective of the study was to analyse factors associated with ART adherence among PLHIV visiting IRT Perundurai Medical College Hospital link ART centre, Tamilnadu, India.

**Methods:** A prospective observational study was conducted during June 2015 to May 2016. All PLHIV receiving ART drugs as per protocol from LAC were included.

**Results:** 139 clients were registered for treatment and follow up till May 2016 in our centre. 31 were transferred to nearby ART, link ART centres. Currently 98 (38 male; 60 female) were utilizing our services. Majority of the patients were on ZLN followed by TLE and ZLE. Most of clients were from rural areas belonging to low or low middle income group. Common occupation was found to be farming and cattle rearing. Most women were housewives. The average age in present study was 38.3 years. Oldest was 73 years old male and youngest 10 years old female. Family support and benefits of ART drugs tops the list of facilitators; supply chain, alcohol issues, family issues were commonly observed barriers.

**Conclusions:** Our results supported the measurement of multiple dimensions of medication-taking behaviours in order to avoid overestimating adherence to ART. Investigation of factors associated with long term adherence would require elaborate and constant follow-ups than in this study period.

Keywords: Adherence, Barriers, Facilitators, Link ART centre, PLHIV

## INTRODUCTION

The Government of India is implementing the National AIDS control programme (NACP) as a 100% centrally sponsored scheme (CSS) through National AIDS control organization (NACO). National AIDS control programme

was launched in 1992 NACP I, presently in NACP IV (2012-2017) to reduce new infections and provide comprehensive care and support to all People Living with HIV (PLHIV) and treatment services for all those who require it. The five cross-cutting themes (quality, innovation, integration, leveraging partnerships and

stigma and discrimination) are focused under NACP-IV.<sup>1</sup> According to NACO Estimations 2012, the adult (15-49 years) prevalence at national level continued its steady decline from the estimated level of 0.41% in 2001 to 0.27% in 2011, total number of PLHIV 23.2 lakh in 2006 to 20.9 lakh in 2011, 86% in 15-49 years age-group, 39% (8.16 lakh) were women, 7% (1.45 lakh) Children. Up to September 2014, from 453 ART centres, 1882991 were registered, 810339 were on first line ART.<sup>2</sup>

NACO aims to provide comprehensive management to PLHIV with respect to free anti-retroviral therapy (ART), psychosocial support to PLHIV, prevention and treatment of opportunistic infections (OI) including TB and facilitating home based care and impact mitigation in stigma free environment by care, support and treatment (CST) component, through service delivery points like ART centres, link ART centres (LAC), link ART plus centre. This ensures the universal access to free and comprehensive CST services in health facilities across the country by dynamic linkages and referral mechanism monitoring, mentoring, decentralization and specialized care. This is possible with linkages of ICTCs, STI clinics, PPTCT services and other clinical departments in all service delivery health units.3

Link ART centres, to facilitate the delivery of ART services closer to the beneficiaries, located mainly at ICTC in the district / sub district level hospitals nearer to the patients' residence and linked to a nodal ART centre within accessible distance. The LAC helps in reducing cost of travel; time spent at the centre and hence helps in improving clients' adherence to ART. Presently, 870 link ART centres are functional all over India. The LACs which perform pre-ART management also are designated as "LAC plus" centres. The clinical team (counsellors, lab technicians, nurses) in LAC, at each of the patient's visits have to impart the importance of adherence. The team has to practice these following key steps with empathy<sup>4</sup>

- Establish rapport and relationship of trust with the patient to develop an individual treatment plan to suit the patient's daily lifestyle events
- Counselling in one or more individual sessions; Pre ART counselling from the date of diagnosis in naïve clients for utmostadherence
- Solving utmost adherence problems and creating a treatment plan
- Describe the treatment programme and importance of adherence, adherence promotion strategies, identification and addressing of barriers to adherence
- Review and refining the strategies and treatment plans
- Assess the client's understanding of the disease and readiness to start
- Review the treatment programme and importance of adherence
- Review proposed adherence promotion strategies.

Adherence "the extent to which the patient follows medical instructions" June 2001; "the extent to which a person's behavior taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (Haynes and Rand - adherence to long-term therapy, a merged version). Suboptimal adherence may rapidly lead to resistance, which can then be transmitted to other people. Antiretroviral therapy should not be denied because of non-adherence behaviour. Health care providers from medical doctors to social workers in the team have to measure the possible reasons and tailor the therapies to safeguard the patients' adherence. Four categories of issues (regimen characteristics, various patient factors, the relationship between provider and patient and the system of care) have usually been found to foresee hitches with adherence to medication.<sup>5</sup> We analysed the adherence level in our centre based on this World Health Organization (WHO) reports.

Universal access of ART, free ART in government sectors enhanced the survival rates, decreased incidence of opportunistic infections, and assured the quality of life more than other chronic illness. But successful treatment result principally determined by on the adherence of the prescribed regimen. PLHA have many impediments for their adherences, health care team to understand the obstacles from clients' and program point of view. Dedicated health care providing teams are providing time and resources to ensure the adherence in all over the countries. In the past, concerns in expanding the ART therapy because of poverty and drug adherence behaviours including the timings of consumption is a major issue in South Africa, but recent studies reported high levels of adherence.<sup>6,7</sup>

In Gujarat , study adapted on SAFETALK "prevention with positives", suggests that several issues (travel and commuting to clinic, fear of possible physical reactions, cost of therapy, laboratory monitoring, role of family members, guidance of treating medical team, etc.) need to be considered before providing ART.<sup>8</sup>

Meena LP et al also concerns in India because of optimizing adherence and minimizing loss to follow-ups (7% loss to follow-up cases). Adherence to ART is a significant determinant of survival. In different part of India various studies to measure the adherence patterns in ART center's.<sup>9</sup>

The most common cause of ART failure is poor adherence. Maintaining the optimum level of adherence is difficult. Adherence should be assessed and routinely reinforced by everyone in the clinical team at each of the patient's visits to the clinic. Studies indicate that 90-95% of the doses should be adhered to for optimal suppression. According to NACO, >95% adherence for 1st line regimens (missing doses <3 doses per month) is compulsorily needed to avoid virological failure and drug resistance. Optimizing adherence and minimizing loss to

follow-up are key challenges against NACO at present. Individual and public health benefits of ART are principally depend on adherence. A hospital based, cross-sectional study from North India concluded that ART adherence fluctuates among individuals and over time, appropriate periodic counselling and inspiration of patients and their family members were necessary to address non-adherence.

Various studies depends on the patient self-reported adherence that distinguishes "optimal" from "suboptimal" adherence based on the 95% threshold, replicates short-term or average adherence and may be an over-estimation, however, a significant relationship between self-report data and viral load. Poor adherence can add to advent of drug resistant viral strains and spread during unsafe behaviours. Improved access to free ART in low-income country settings has contributed to an interest in treatment adherence. 11-13

### **METHODS**

The aim of the study was to analyse factors associated with ART adherence among PLHIV visiting IRT Perundurai Medical College Hospital Link ART Centre, Tamil Nadu, India. This was a prospective observational study conducted during June 2015 to May 2016. We undertook a prospective review of catalogues of all PLHIV on ART from our centre. The study protocol was approved by institutional ethical committee.

All PLHIV on ART from LAC, in our hospital have been included, during the study period. In this period expired PLHIV, transferred to other link ART centre / ART centre and lost for follow up more than 6 months were excluded from study.

# Methods

In our institution (IRT Perundurai Medical College, Perundurai, Erode District, Tamilnadu, India) we provide ART care, follow up and continuum of care through LAC by ICTC staff from September 2010. In ICTC we preserve data of PLHIV on Link ART registry as per the NACO guidelines, which are regularly reviewed by Tamil Nadu State AIDS control society in the prescribed format. In this study, we intended to analyse factors associated with ART adherence among PLHIV visiting centre.

Stocks and supply chain of ART drugs maintenance and dispensing were followed as per the NACO guidelines in ICTC after clinical review by medical officer in OPD. We ensured the availability of clinical team from 8 am to 4 pm. In each visit, people undergo counselling, clinical assessment, monitoring regarding opportunistic infections, need based laboratory investigations, and guidelines based CD4 count. In this process we offered counselling to ensure complete adherence to ART regarding doses, timings, before or after food, morning or

night, discussion of possible side effects and simple ways to address side effects as per the national protocol. In the need based special circumstance we ensure medication supply through the family members. We regularly follow the clients through outreach workers, mobile phones, emails, letters and peer group contacts. In our institution inpatient care and treatment is available for needed in free of cost. All the needed clinical facilities are available in the institution.

#### RESULTS

In Table 1, there were total of 139 clients, 22 in 2010, 12 in 2011, 6 in 2012, 51 in 2013, 36 in 2014, and 9 in 2015, 3 up to May 2016 registered in our centre. 31 were transferred to nearby ART, link ART centres during this period as per their request. Currently 98 regulars (38 male; 60 female) utilizing our centre. Transferred out denotes peoples referred or opted out to other LACs or ART centres. In lost for follow up group, patients not reporting to our centre for last 6 months, we are unable reach them by cell phones, home visits by counsellors, outreach workers, various other health care workers, they are also not reached any other LAC or ART centres.

Table 1: Client details.

| Client details     | Male | Female | Total |
|--------------------|------|--------|-------|
| Presently on ART   | 38   | 60     | 98    |
| Transferred out    | 18   | 13     | 31    |
| Lost for follow up | 3    | 1      | 4     |
| Deceased           | 5    | 1      | 6     |
| Grand total        | 64   | 75     | 139   |

In Table 2, in terms of treatment, majority of patients were on ZLN ( zidovudine, lamivudine, nevirapine) followed by TLE (tenofovir, lamivudine, efavirenz) and ZLE (zidovudine, lamivudine, efavirenz) regimen.

Table 2: ART regimen subgroups.

| ART regimen      | Male | Female | Total |
|------------------|------|--------|-------|
| ZLN              | 30   | 43     | 73    |
| TLE              | 7    | 12     | 19    |
| ZLE              | 1    | 5      | 6     |
| Presently on ART | 38   | 60     | 98    |

In Table 3, we narrated socio demographic factors. Most of them were from rural areas and few from nearby Erode Corporation. All of them belonged to low or low middle income group. Majority were doing farming, cattle rearing. Most of the women were housewives. In our study group 9 were couples, single were 80, legally separated, widowed, and 2 children. The average age in present study was 38.3 years. Oldest was 73 years male and youngest 10 years female. In Table 4, in the facilitating factors associate for adherence, the family support and benefits ART drugs were tops the list.

Table 3: Socio demographic factors.

| Social demographic factors | Male<br>38 | Female<br>60 | Total<br>98 |
|----------------------------|------------|--------------|-------------|
| Residence                  |            |              |             |
| Rural                      | 36         | 58           | 94          |
| Urban (Erode corporation)  | 2          | 2            | 4           |
| Socioeconomic class        |            |              |             |
| Low                        | 32         | 55           | 85          |
| Middle                     | 4          | 3            | 7           |
| High                       | 0          | 0            | 0           |
| Occupation                 | 38         | 60           | 98          |
| Agricultural workers       | 14         | 16           | 30          |
| Daily wagers / Coolie      | 10         | 10           | 20          |
| Business persons           | 8          | 5            | 13          |
| Office workers             | 4          | 2            | 6           |
| Unemployed                 | 2          | 10           | 12          |
| House makers               | 2          | 27           | 29          |
| Family status              |            |              |             |
| Couple                     | 9          | 9            | 18          |
| Unmarried / divorced       | 29         | 51           | 80          |

In Table 5, barrier factors associate for adherence the supply chain, alcohol issues, family issues were tops the list.

**Table 4: Facilitators.** 

| Factors enhancing adherence ( facilitators )                          | Male<br>38 | Female<br>60 | Total<br>98 |
|---|------------|--------------|-------------|
| Support of family and friends   | 36         | 59           | 95          |
| Good relationship between patient and core clinical team              | 30         | 59           | 89          |
| Understanding the relationship between adherence and CD 4 count       | 34         | 55           | 88          |
| Symptoms & opportunistic infections OIs                               | 35         | 58           | 93          |
| Less frequent dose  | 36         | 59           | 95          |
| Fewer pills per day   | 37         | 59           | 96          |
| Fewer dietary restrictions  | 30         | 50           | 80          |
| Fitting medication to individual's lifestyle                          | 37         | 59           | 96          |
| Beliefs that medication is effective                                  | 38         | 60           | 98          |
| Positive beliefs regarding the efficacy of antiretroviral medications | 38         | 60           | 98          |

Table 5: Barriers.

| Factors decreasing adherence ( barriers )                                 | Male 2 | Female 2 | Total 4 |
|---|--------|----------|---------|
| Stress of childcare, feminine issues                                      | 0      | 2        | 2       |
| Low income  | 2      | 2        | 4       |
| Lack of social and family support   | 1      | 2        | 3       |
| Asymptomatic patients   | 2      | 0        | 2       |
| Close monitoring; severe lifestyle alterations                            | 2      | 0        | 2       |
| Adverse events in the family  | 2      | 2        | 4       |
| Adverse effects of treatment  | 2      | 0        | 2       |
| Forgetfulness   | 2      | 2        | 4       |
| Life stress   | 1      | 2        | 3       |
| Alcohol use and drug use  | 2      | 0        | 2       |
| Depression, hopelessness and negative feelings                            | 2      | 1        | 3       |
| Beliefs that alcohol and drug use interfere with medications              | 2      | 2        | 4       |
| Stopping ART, while taking other medications for other illness            | 2      | 0        | 2       |
| Sensed like drug was poisonous /injurious / desired to evade side effects | 2      | 0        | 2       |
| Financial constrains for travel   | 0      | 2        | 2       |
| Forgot or avoid to take medicines when away from home                     | 2      | 1        | 3       |
| Logistic and supply chain issues in LAC                                   | 2      | 2        | 4       |

# **DISCUSSION**

The Medical monitoring project study reported non-adherence 13% to dose, 27% to schedule, 30% to instructions (during past 48 hours), and emphasized the measurement of multiple dimensions of medication-taking behaviour of PLHIV.<sup>14</sup> In a study from Ethiopia,

participants were adherent to doses than schedule because of their perception and beliefs about timings.<sup>15</sup> In our centre, clients overall adherence to dosing was much better than to timetable and advices.

Multiple studies narrated patient age, middle level of monthly income, higher annual income, and increased self-efficacy were contributory for good adherence. Disclosure status and family support, family attachment and family functioning, changeability, partners' motivation, experiencing peer support were producing healthy atmosphere for optimal adherence. <sup>11-13,16</sup> We also observed better family atmosphere resulted in enhanced adherence.

In the health system, factors like health care workers unflinching support, satisfaction with care provider, positive provider-patient relationship, continuous information provision, and maximum utilization of health services were noted as motivators in studies. <sup>17,18</sup> In care and treatment aspects, fewer opportunistic infections, depressive symptoms, individuals' tablet taking behavior were the corner stone of good adherence. Provision of free treatment and medications improved adherence in all developing nations. <sup>19,20</sup> Our institution's three decade experience in PLHIV care reflected similar trend, after the provision free HAART, treatment seeking and continual has immensely improved. <sup>21,22</sup>

In pharmaceutical issues, simple regimens, lower daily dosing frequency, once a day pills, health maintenance on single regimen without side effects and failure were documented as facilitators all over the world.<sup>23</sup> In monitoring, increases in CD4 count from 50 to 150 cells/mm<sup>3</sup> at the end of first year was a motivating factor.<sup>20</sup> Our experience replicated the universal trend, but regimen change, pills in different color or containers faced early hitches in experienced clients.

The PLHIVs' commitment to treatment outcome, self-efficacy, concerns about effectiveness and safety, beliefs in life- affirming properties were narrated as good adherence factors. In rural Uganda, SMS reminders with real-time adherence monitoring were interpreted as signs "caring" by health system. HocCoy K et al described higher annual income and increased self-efficacy with ≥95% adherence. Harkhand study concluded that adherence to ART was allied with an increased survival chance of PLHIV, determining the need for interventions to improve adherence and early initiation of ART. In our center, linkages between the peer groups, social workers, and health care team played vital role in achieving appropriate adherence.

Comprehensive assessment of non-adherence should include measures of dose, schedule, and instruction, because accurate information is crucial for evaluating both the effectiveness of ART regimens and interventions designed to increase adherence.<sup>27</sup> Studies all over the world documented fear of disclosure and stigmatization due to disclosure, specific attitudes towards ART and HIV, experiencing physical adverse events in hospitals, health service discrimination, wrong awareness towards ART were key barriers in PLHIV care, especially in perception point.<sup>28,7-15</sup> We had eight clients with similar experiences, utilizing our center for services due to their felt stigma in native places. Poverty, lack of awareness,

and social stigma associated with infection muddle an already complicated situation. Individual lifestyle, age, genetic make-up, food and shelter insecurity, financial constraints, alcohol and festivity drug use, poor self-reported health, living in outskirts, being away from home, being busy were documented as individual barriers.

Client's forgetting attitude, forgetting tablets and appointments because of substance use, ranking drug use over ART were documented as behavior level barriers. 32,33 4/98 due to forgetfulness and 2/98 clients due to alcohol related issues were therapy non-adherent seen in our client group. In treatment aspects, taking regimens with more than one ART dose per day, certain types of ART regimen like protease inhibitor containing regimens, drug toxicities, adverse effects of ART, too ill or healthy and viral load level were notable worries. 11,34 Our two clients stopped because of these issues; now, restarted on suitable ART after complete clinical and social assessment.

Health care system factors like quality of health care, long counseling gaps, run out of pills due to supply chain issues, and unhappy hospital atmosphere were reported obstacles. Four of our clients attributed their non-adherence to drug supply chain issues. A meta-analysis revealed, co-morbidities, medication complexity and cognitive impairment reduce adherence. Significant population with infection have been living for many years, the reason they have successfully survived to older age is by virtue of better adherence throughout their life time. Under-diagnosis and under-treatment of depression may hamper adherence among infected patients of all races. Colored race were considerably related with poorer adherence, which was not changed by depression. 36

A clinician-initiated, open appreciation of social and realistic hurdles of daily adherence for young people would assist more transparent discussion and persuade younger to non-adherence and other problems they may be facing with their regimen, to decrease health harms and poor adherence in longer-term.<sup>37,38</sup> In a program based study concerns about partner support, feeling healthy, needing time to accept one's serological status, religious beliefs, gossips and transport issues were commonly reported barriers. Even within context of universal healthcare gender-specific interventions were needed to improve adherence to ART among IDU women.<sup>39</sup> Nyamathi A et al revealed women with support from spouses and parents were more adherent. 40 In our center, women with supportive family milieu were adherent, taking care of themselves and family members.

Recent advances in HIV treatments have transformed nature and progression of HIV/AIDS to a "chronic" disease, shifted the perception from fatal to chronic manageable illness and improved the quality of life. The integration of ART, RNTCP, PPTCT services under

single roof in existing government and public sector hospitals along with refresher and reinforcement training, improving the health system administration were the need of the hour. This will ensure the efficient early care and treatment, decreased lost for follow-up, and provision of better topographical care coverage with all possible resources, from health to social departments, from sub centers to medical colleges. Our day to day experiences endorsed PLHIV care and treatment like chronic non communicable diseases like hypertension, diabetes. Several measures of adherence to have been amalgamated and many target interventions to resolve barriers should be executed to reduce ART resistance therefore to achieve the best quality of life in PLHIV.

#### CONCLUSION

Achieving 100% adherence for all patients on ART is a great challenge. Long counselling gaps, wrong perception towards ART, presence of depression, and nonsatisfaction with health services were found to be barriers to adherence. Timely detection of non-adherence behaviour and appropriate monitoring of patients, difficulties with ART could potentially help patients to maintain adherence and improve treatment outcomes. Adherence is a process, not a single event, and support must be integrated into regular clinical follow-up. In order to maximize the benefits of ART, patients should be educated on the need of adhering to right dose in right time as an intervention against barriers to adherence. Utilization of multiple measures of adherence to be incorporated in the care plans. Multifarious target interventions focus to resolve the barriers to adherence should be implemented. Our results supported the measurement of multiple dimensions of medicationtaking behaviours in order to avoid overestimating adherence to ART.

Limitation of the study was that this was an observational study, we were depend on participants version, unable to cross verify the drug taking behaviour (time and dosses, before or after food, other instruction given during counseling), only bill counting is possible in reality . Study limited only with participants from our link ART centre, cannot be generalized. Investigation of factors associated with long term adherence would require longer follow-ups than our study. We request the researchers to scale up similar one in all centres to prevent the resistance to ART drugs and improve the quality of life.

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