



## Factors influencing adherence to Anti-retroviral therapy in early and late treatment HIV groups in a teaching hospital, India; a qualitative cross-sectional study

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### Abstract

**Background:** With the growing success of anti-retroviral therapy (ART), adherence to drugs is considered a major keystone in the management of HIV/AIDS. Adherence is influenced by the determinants of behavior that reside both within and outside of the patient. The aim of the study was to gain a deeper understanding of the factors that influence the adherence to ART among HIV patients, registered in a referral center, India, a resource-limited country.

**Materials and Methods:** Semi-structured interviews, guided by a questionnaire based on literature review, were undertaken among two groups of twenty patients (early ART < 6 months and late ART ≥ 6 months) and their family members focusing on the adherence factors. These factors included medication, caregiver/family/society, health care service, and patients' beliefs related factors. These interviews were transcribed and analyzed using the qualitative methods.

**Results:** We found that in both groups the adherence was influenced by many barriers like fear of stigma, side effects of drugs, depression, regimen complexity, disbelief, and lack of confidence on the cure. Whereas, it was facilitated by motivation and coping behaviors, reminders, family responsibility/support, seeing examples of successful treatment, and proper education. The studied factors and with the help of literature reviews, we constructed a conceptual model for our health care center to recognizing all possible influencers to adherence and promoting interventions.

**Conclusions:** The study elucidates high level of self-reported adherence in the resource-limited settings. Both barriers and facilitators to adherence are recognized in both groups of ART, which need to be quantified in future studies. A conceptual model is created which will identify possible influencers and provide patient-centered quality services to improve ART adherence in the long run.

**Key words:** AIDS; Highly active ant-retroviral therapy; Quality appraisal; Questionnaire; Self-reported adherence

### Introduction

According to UNAIDS epidemic update, HIV has killed more than 25 million people since it was first recognized in 1981. With availability of highly active anti-retroviral therapy (HAART), it is no longer a fatal disease, but a manageable chronic condition. The major factor determining the success of HAART (onwards it will be abbreviated as ART, not HAART) is the sustained and optimum adherence to therapy [1,2]. Adherence is second only to CD4 count which determines the progression of HIV and is considered as "Achilles heel of HIV management". Research indicates that high levels of adherence are necessary for reliable viral suppression, prevention of drug resistance, and halting

disease progression [3-5]. With 95% adherence, viral suppression to below detectable levels occurs in 80% of patients. However, a fall in adherence to 70% (i.e. 25% less than optimal) drastically decreases viral suppression to 33% [6]. However, there are many factors which modify the adherence, are to be known.

There have been concerns to adhere in resource limited settings, especially in Africa and India [7]. Although studies from these settings had documented high levels of adherence; however, a systematic review reported barriers and facilitators of adherence are different in developing countries from developed one [8]. In India, adherence is a challenging issues especially when ART is being provided free of cost by the government. Unfortunately, 25% of patients discontinue their initial treatment because of toxic effects, non-compliance, or treatment failure within the first 8-months of therapy [9]. Self-reported adherence to first-

line ART in India is currently around 70-80% [10]. Adherence is largely influenced by a set of core determinants of behavior that reside both within (e.g., personal motivation) and outside (e.g., local belief systems about the treatment or disease) the patient and these core determinants are understood most efficiently by focusing on one's perceived barriers and facilitators of adherence. By focusing on adherence problems reported at the clinic visit will help providers customize interventions to improve adherence. In India, there are no adequate literatures on adherence and the factors influencing it. Henceforth, we did an exploratory qualitative study using in-depth interviews with the patients and their family members/caregivers, who attended the HIV-clinic, to understand the factors influencing ART adherence with the aim to develop a locally appropriate adherence model that would give an overview of the factors and promote appropriate interventions.

### Materials and Methods

The study was conducted in ART clinic at a referral center in Northern-India over two years time period. The study aimed to

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**Table 1:** Grades used for Semi-quantitative Expression of Observations

Proportion of Respondents	Grades	Adjectives used
<25 %	1 +	Few
25 - 49 %	2 +	Almost half
50 – 74 %	3 +	Majority
75 – 89 %	4 +	Most
>90 %	5 +	Almost all

explore the factors influencing the adherence to ART using semi-structured interviews with HIV patients and their family members/caregivers and to develop a locally appropriate adherence model for promoting appropriate interventions. We included patients who were registered and being treated in ART clinic of this hospital with age more than 18 years, and excluded patients having neurological dysfunction including eye/ear problems for better interviews, assessed clinically by Glasgow Comma Score (<21, excluded), and seeing past neurological records. Patients were recruited from the clinic when patients were coming for follow up visit. We divided the study participants into two groups (early ART, < 6 months on therapy and late ART, > 6 months on therapy) as per treatment records to analyze better among adherence factors and accordingly prepare a model for the implementation. Each group included 20 patients for analysis. We also made an attempt to include one family member or caregiver of each patient in interviews. So, in reality, total participants were 80. The interviews were conducted in the ART clinic in a separate isolated consulting room using open-ended questions in patient's local language (Hindi). The questionnaire was developed after reviewing the literature and by conducting trial interviews in few patients. After reviewing the literature on adherence to ART, we developed the questionnaires with 5 broad categories: 1) medication related factors, 2) family/society related factors, 3) healthcare service related factors, 4) patient's beliefs and expectations, 5) other factors [11-13]. These factors were real variables for this study. In addition, accompany family members/care givers were also questioned about factors affecting the adherence. The interviews were audio taped and transcribed to verbatim transcripts in English. These transcripts were read many times to notice and identify the factors. These identified factors were coded after discussing with

investigators. As we found the new codes in each interview, its presence was intensively searched in older interview by reviewing the records and enquired in further patients by editing the questionnaire. Thus we saturated the properties of each code with more data and made them more focused and analytic as we proceeded. At the end, the patients were enquired about their medications left over the last one month and self-reported adherence rate was calculated using below formula:  

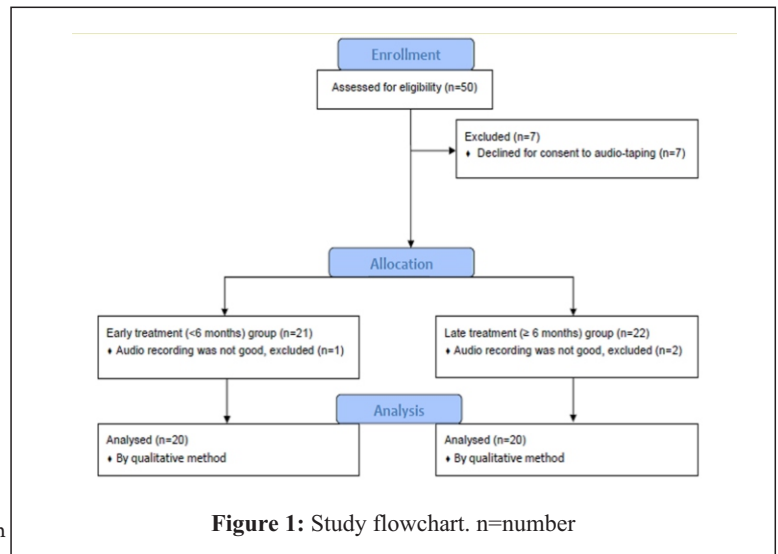
$$\left( \frac{\text{Drugs to be taken per month} - \text{Drugs left in a month}}{\text{Drugs to be taken in a month}} \right) \times 100$$

Drugs to be taken in a month

The socio-economic classes of the patients were calculated by using Kuppuswamy's modified SES scale, dependent on the patient's annual income, educational status and occupation. All qualitative and quantitative data were collected and handled appropriately. The adherence factors were compared across the groups (early vs. late ART) and graded in a semi-quantitative form (Table 1). This approach allowed us to systematically identify key themes and patterns of responses among the patients to understand appropriate context specific and culturally sensitive influencers to drug adherence. The study protocol was approved by the institutional review board. Data collection procedures were completed with ensuring subject confidentiality. All the participants were informed that their responses were being recorded, confidential, anonymous, & not being judged. Informed consent was taken from all.

**Results**

**Baseline Characteristics:**



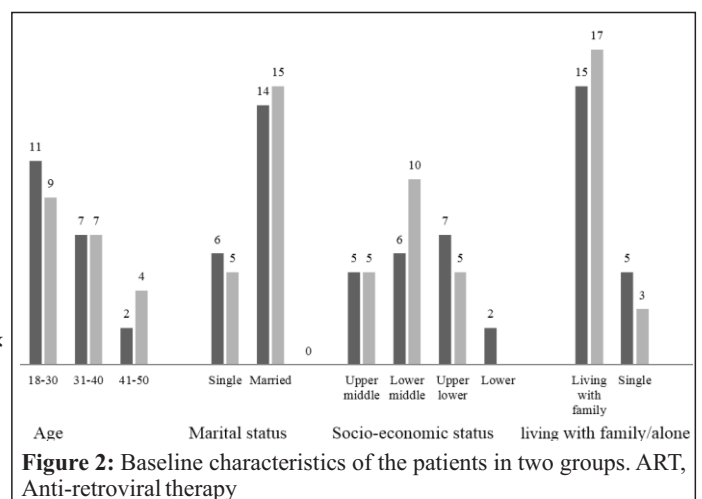
**Figure 1:** Study flowchart. n=number

Twenty five patients were enrolled for each study arms. Few patients did not give consent for audio taping, a total of 20 interviews in each arms were selected for analyzing. Figure 1 showed the study flowchart. Groups were similar in major baseline: 20 in early ART (< 6 months) and 20 in late ART (≥ 6 months); 20 (50%) men and 20 (50%) women. Most of the respondents were in the age group 18–40 years. The majority was married, living with their families; belong to lower middle and upper lower of the socio-economic class. Important patient variables of two groups are summarized in figure 2. The adherence rate of early group was 96 % (males) and 98% (females); while in late group, it was 100% (males) and 96% (females).

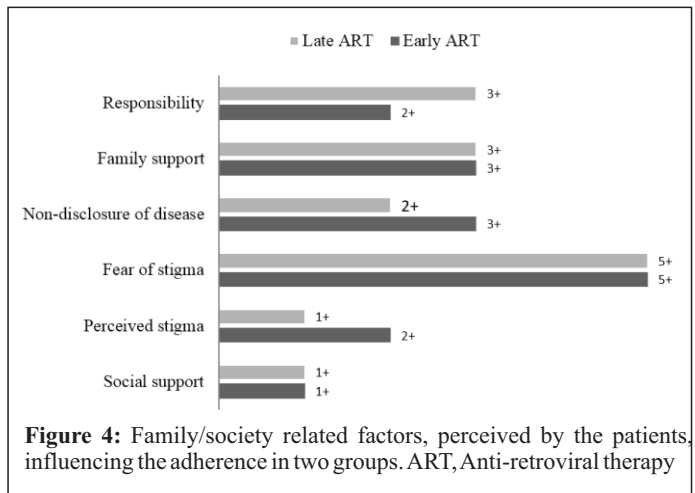
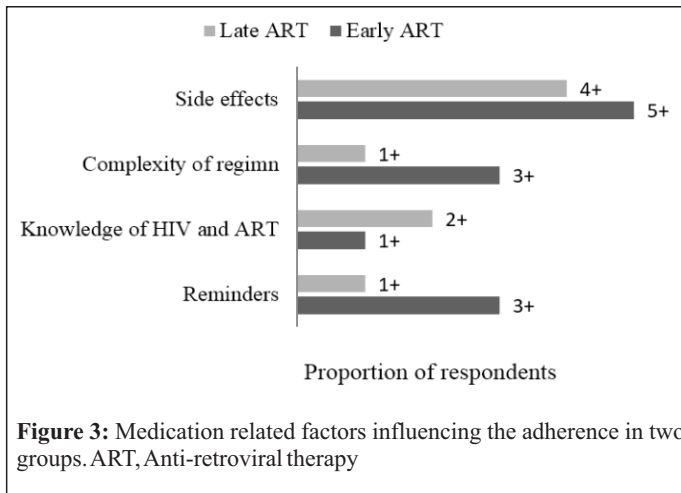
**Primary outcome analysis:**

The major adherence factors were:

**Medication related factors:** Almost all (5+) in two treatment groups had reported minor side effects after starting ART. However, few (1+) told that they had compromised medicines due to medication related factors (Figure 3). "I felt mad and nauseating on anti-HIV medicines...but it subsided over a period of



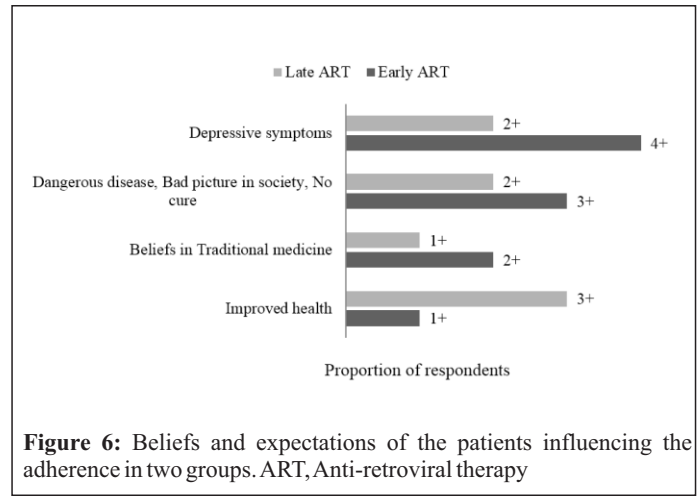
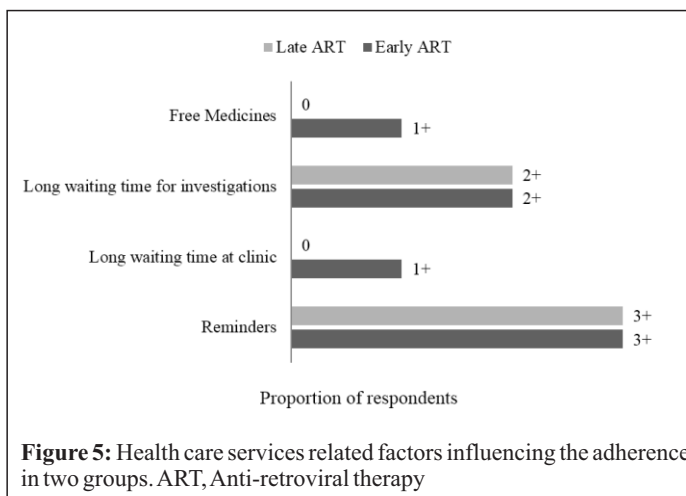
**Figure 2:** Baseline characteristics of the patients in two groups. ART, Anti-retroviral therapy



time” Majority (3+) in early group and few (1+) in late group were taking other group of drugs like prophylactic drugs for opportunistic infections, anti-tubercular therapy, antihypertensive, oral hypoglycemic agents. Few of them had raised concern regarding the complexity of the regimen and occurrence of more side effects with more drugs. Few (1+) of them had admitted that they missed medications for 1 or 2 doses. The various reasons told by them were simply forgetfulness, lack of confidence on ART, improved health, using other drugs, and cost of the medications. “...My child had exams...I was teaching him...it had become late and we missed to take dinner and drugs as we forgot” Family/society related factors perceived by the patients: Family supports, responsibility, care giving, disclosure of disease status, and social stigma were the major factors found to influence the adherence (Figure 4). Approximately half (2+) of the patients in early group were the head of their respective families and took valuable decisions regarding health. Majority (3+) of them were of opinion that they had good support in their family. Whereas

majority (3+) in late group were head of their respective families, involved in decision making, and had good support in their family. “I am head of my family... there are some harassments too... my wife helps me a lot” Few (1+) of the patients in early and almost half (2+) in late group told that they had compromised their medication due to stress related to family events. Few (1+) in late and almost half (2+) in early group had raised concerns to take their medication publicly. “...2008 December...My sister’s marriage...being eldest in the family I had lot of responsibilities to make arrangements...” Majority (3+) in early and almost half (2+) in late group had not disclosed their disease status to anyone. Few (1+) of them had disclosed to only partners and friends. Almost all (5+) in early and late group had expressed fear of stigma, as a bad picture in the society, a major reason for not disclosing. However, almost half (2+) in early and few (1+) in late group had expressed concerns that they were stigmatized after disclosing their disease to others. “I told about my disease to a close friend, he told to other friends, since then they feared to even shake hands with me” Health care service related factors:

Few (1+) of the patients in early group raised concern about the quality of free drugs (ART) provided in public hospitals (Figure 5). “I don’t believe government will give good-quality medicines for free.” Almost half (2+) in both early and late groups had raised concerns regarding difficulty in getting investigations done. Few (1+) in early group had expressed concern that they had to wait for a long time in the clinic, leading to negation towards drug adherence. “After coming here we had to wait a lot... then for investigations we had again to wait for the whole/next day... it will be difficult for us to get fresh food and water” Majority (3+) in early and late groups had told that they use reminders like marking on calendar and counting the pills for planning next appointment. Beliefs and expectations of the patients: Majority (3+) in early and almost half (2+) in late group opined that HIV is a dangerous disease, had bad picture in the society, and no cure. They also felt guilty in few occasions (Figure 6). “When I was told that I am having a disease... there are no curable drugs and I think



it's the end of my life"

Most (4+) in early and almost half (2+) in late group had told that they had minor depressive/low mood symptoms after they were found to have disease. However, they had not attributed those symptoms to their therapy. Almost half (2+) in early and few (1+) in late group told that they believed in traditional medicines, but majority (3+) in late group told that they improved in health after taking ART. "I heard about Indian local medicines curing big diseases... same with HIV... so I stopped them"

**Other factors:**

Various structural barriers were described here. Few (1+) of the patients expressed concern that they had to come from a long distance, had problems in arranging accommodation, and transport fares. Very few (< +1) patients in early group told that they are new to the hospital and need someone to accompany them.

"My house is 1500 kilometers from here...I come by bus/train...it is very difficult for me to come here ... I need to stay in my friend's house here..."

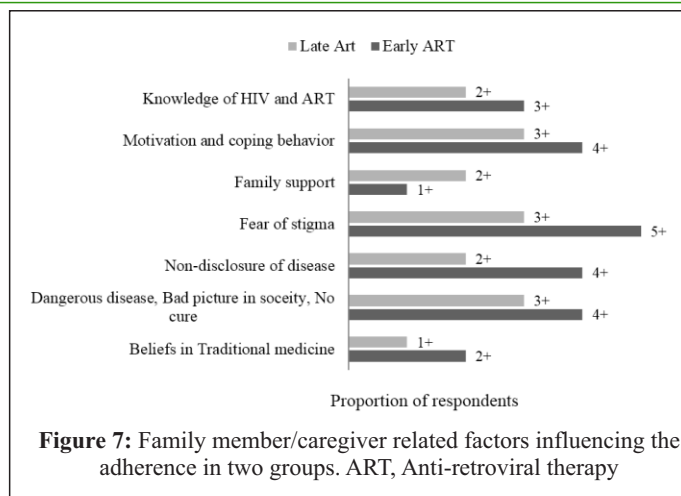
Few (1+) of them had discussed about some factors that hinder clinic visit like problems in taking leave, loss of wages and are concerned to leave the clinic early.

**Family member/Caregiver related factors:**

Most (4+) of the patient accompanier's in early and majority (3+) in late group had good motivation and coping behavior (Figure 7). "I always tell my husband to take medicines in time and tell him that we had to live for our children"

Other indices were more often similar to patients' own responses, which included knowledge about HIV/AIDS, family/social support, fear of stigma, non-disclosure of diseases, beliefs in traditional medicines, etc. This supported that both patient and their family member/care taker were truthful in their words.

In the end, different factors distinguished as barriers and facilitators to ART adherence in both groups were arranged in a table format as per respondents' answers to the questionnaires (Table 2).



**Figure 7:** Family member/caregiver related factors influencing the adherence in two groups. ART, Anti-retroviral therapy

**Discussion**

The study said overall self-reported mean adherence rate to be > 95% in both early and late groups of ART, even in the resource-limited settings that present unique challenges to adherence. The overall major (>50% respondents) barriers of adherence to therapy were fear of stigma and side effects of drugs in both groups; depression, complexity of regimen, and non-disclosure of disease or disbelief in early group; and lack of confidence on cure or doubt on ART in late group. Similarly major facilitators of adherence included motivation and coping behaviours,

**Table 2:**Major barriers and facilitators influencing ART adherence in two groups

Early – ART (< 6 months):	Late – ART (≥ 6 months):
<b>Barriers</b>	
Fear of stigma (5+)	Fear of stigma (5+)
Side effects of drugs (5+)	Side effects of drugs (4+)
Depression (4+)	Doubting ART/no confidence (3+)
Complexity of regimen (3+)	Non-disclosure of disease (2+)
Non-disclosure of disease (3+)	Stress at Job (2+)
Family responsibilities/support (3+)	Depression (2+)
Doubting ART/no confidence (2+)	Waiting time for investigations (2+)
Belief on traditional medicines (2+)	Stigmatization (1+)
Stigmatization (2+)	Long distance from clinic (1+)
Waiting time for investigations (2+)	
<b>Facilitators</b>	
Motivation and coping behavior (4+)	Family responsibilities/support (3+)
Reminders to take medicines (3+)	Experiencing improvement after treatment (3+)
Reminders for clinic visits (3+)	Reminders for clinic visits (3+)
Knowledge of HIV/ART of family members/care givers (3+)	Motivation and coping behavior (3+)
Family responsibilities/support (2+ or 3+)	Knowledge of HIV/ART of family members/ care givers (2+)
Knowledge of HIV/ART (2+)	Reminders to take medicines (1+)
Social support (1+)	Knowledge of HIV and ART (1+)
	Social support (1+)
<b>Note: Values in bracket represents Grades used for semi-quantitative expression of observations as shown in the table 1.</b>	

reminders for clinic visit, and family responsibilities/supports in both group; while knowledge about HIV/ART among family members or care takers had important role in early group and experiencing improvement after treatment played a role in late ART group. These characteristics and literature reviews helped in making a conceptual adherence model for our health centre. This model will help in early recognizing various influencers of adherence and subsequent implementation of interventions to promote the same. Our study had several strengths. It was a qualitative study, a superior to quantitative one since it allowed the patients to tell the researchers what they believed in factors as barriers or facilitators. Some of the variables, in particular the factors related to social support and health system, had not been studied previously. The conceptual developed model was of increasingly significance towards creating awareness of adherence among HIV health care providers. It was also the first study to find the differences in adherence patterns

between two treatment (early vs. late) groups. In our study, self-reported mean adherence rates were high among the two groups (early and late ART) and were consistent with previous studies from developed world [6, 14-16]. However, this method simply overestimates the rate. Therefore we need more objectifying method (e.g. electronic methods) to know the real rate. There are multiple known modifiers for the adherence especially in developing countries like India; those include factors related to the medication, the caregiver/family/society, the patient's beliefs, the healthcare, and others [7]. Among medication related factors, regimen complexity, side effects, and poor knowledge on drugs were common barriers to adherence in previous studies [17-19]. Forgetfulness and regimen complexity were quoted as the common reasons for lack of adherence in studies [19-21]. However, these barriers can be used in developing adaptive coping statements like "The side effect implies that the medicine is acting and killing my HIV". Similar approach

was tested in United States using cognitive behavioral therapy [22]. Majority (3+) in early ART group (Figure 3) were using reminders like alarms, cell phones, messages for scheduled intake of drugs, which will improve the adherence [23]. This difference might explain the habituation to medication in late ART group over a period of time and more adherence rate. Among the patients and family/caregiver/society related variables, patient's responsibility/dependence in a family, family and social supports, non-disclosure of disease status, stigma, disbeliefs, and depressive symptoms in patients were found to be common influencers for adherence in studies [24-27]. Fear of stigma was more than the perceived stigma among our study groups; both can be removed by proper education only. In a study at AIIMS, we found that emotional and fatigue symptoms were more common than physical symptoms among HIV patients which might be due to somatization/ poor coping behavior in this group [27]. In the

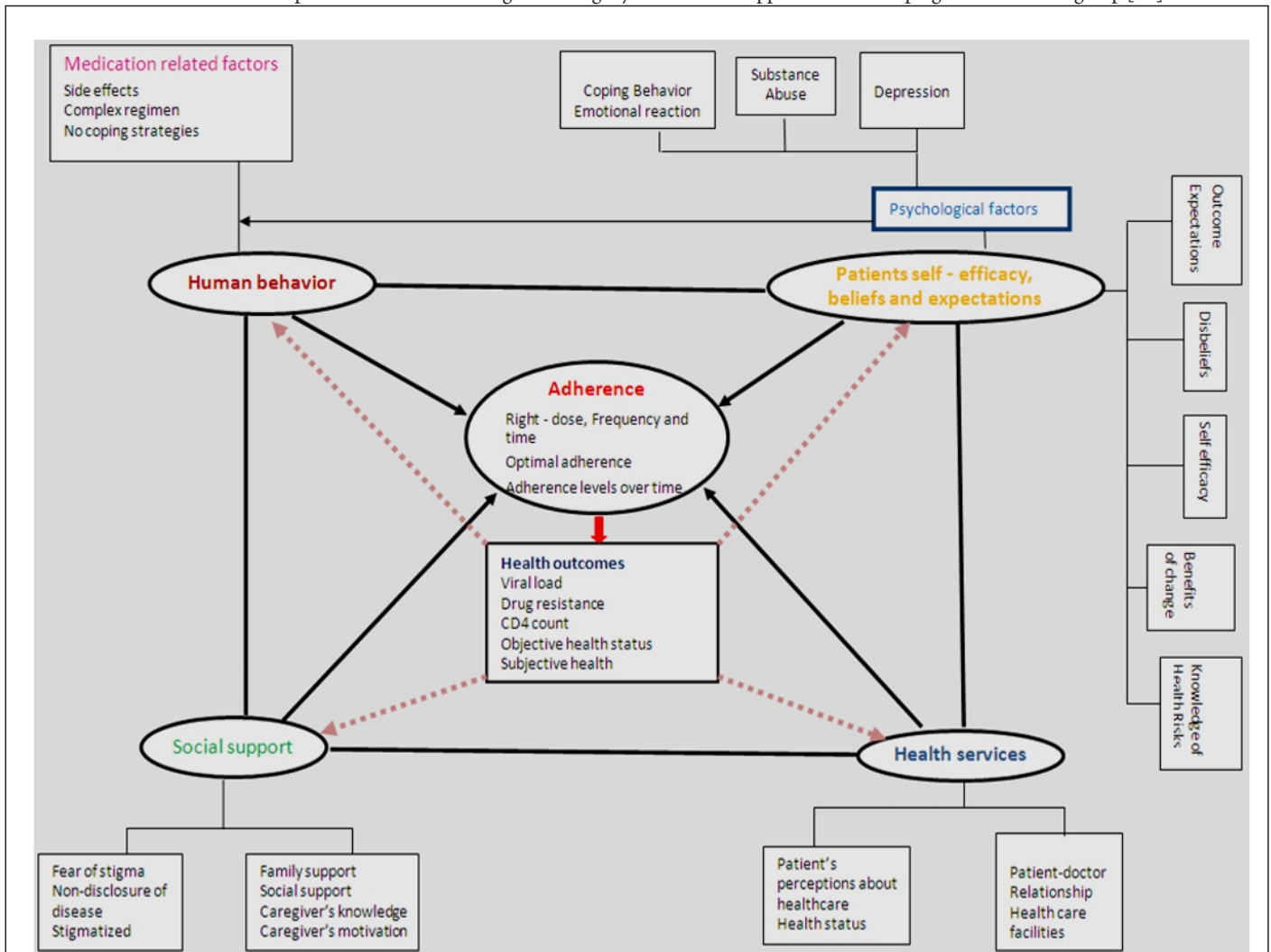


Figure 8: A conceptual model for factors influencing ART adherence in a resource-limited setting. ART, Anti-retroviral therapy

present study we also found more depressive symptoms among HIV patients early on therapy. However these depressive symptoms may not be due to drugs but is a strong barrier to adherence [28]. Thus early identification and management of depression is needed to maintain high levels of adherence. Patients who were improved on ART can be used as facilitator in this type of barrier.

There is scarcity of studies related to healthcare system as influencer to ART adherence. In this study, all participants appreciated the study center's model of care which had a positive effect on adherence behavior. Few (1+) patients doubted the quality of free drugs and preferred to buy them and it is an important disbelief, indicating the need for appropriate education to alleviate their concerns. Majority (3+) had also expressed concerns regarding long waiting time for investigations and clinics appointments, and skipped their food, thus provoking the need of the hospital administration to take necessary steps. Among structural barriers, issues like cost, long distance from the clinic, taking leave, loss of daily wages were reported by few (1+) patients. Similar findings were reported to be the major issues for non-adherence in the first qualitative study from India [10]. But these factors were uncommon in the current study, which might be due to the effect of wide expansion of ART clinics throughout India, providing ART for free of cost through NACO.

After analyzing the qualitative data and reviewing the literatures we developed a

theoretical conceptual model (Figure 8) on the factors influencing ART adherence. It had inter-related various barriers and facilitators, which gave an overview on the factors influencing adherence. In summary, this model suggested that better adherence was associated with more accurate information about one's regimen, stronger personal and social motivation, fewer barriers to healthcare approach, and stronger adherence behavioral skills. In this model we also found support for each of the propositions in the literature [12]. This model will help all HIV health care providers in increasing their knowledge and practices towards ART adherence.

It had several important limitations. First, it recruited small number of patients with relatively common socio-cultural lifestyle from single center, where HIV/ART services were available freely. Thus limits generalization to whole group of patients from India/world. Second, it used self-reports for assessing adherence, which had the risk of recall anomalies and overestimating the adherence rates [8,15,16]. However, there is no gold standard method for assessing adherence and self-reported method is a relatively simple and efficient method useful in resource-limited settings [29]. Objective methods are superior and recently electronic counter devices are producing more accurate results [30]. Third, the adherence factors were dynamic and can change over a period of time but were analyzed using single time interview. A well designed prospective and descriptive trail using both

qualitative and quantitative analysis helps in better understanding the links between adherence, virologic response and antiretroviral resistance.

In conclusion, the study establishes encouraging high level of self-reported adherence in the resource-limited settings, which need to be proved objectively by electronic counter system. In early/late ART group, the different barriers of adherence are there, so they need facilitators to improve adherence. Few patients had irregular adherence and had important recognizable factors influencing it, thus highlighting the importance of their identification and the potential for improving adherence to ART, based on the developed conceptual model. Thus the study helps in promoting interventions and providing patient-centered quality services to improve adherence to drugs and clinic visits. Further research is needed to quantify these findings and accordingly tailoring interventions are warranted to improve the adherence.

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