Determinants of treatment adherence among the patients receiving treatment in the ART centre of a tertiary hospital in Kolkata, West Bengal, India
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ABSTRACT

Background: WHO recommended adherence of 95% or more to antiretroviral therapy for better outcome in terms of general well-being and decreased chance of drug resistance. This study was conducted with the objective of describing the factors associated with adherence pattern to ongoing ART regimens in adults with HIV/AIDS in R. G. Kar Medical College and Hospital (RGKMCH), a tertiary hospital in Kolkata, West Bengal, India.

Methods: An observational, descriptive cross-sectional study was conducted on the adults receiving treatment at the ART centre of R. G. Kar Medical College, Kolkata. Patients above 15 years of age, who received at least one year of treatment before the day of the interview, comprise the study population. Sample size was 279. We tried to find out any association between adherence level and factors like socio-demographic profile, treatment profile, lifestyle pattern etc. applying bivariate analysis, Chi square test, multiple logistic regressions. Data were analyzed using IBM SPSS (version 20).

Results: Different factors like employment status, monthly income, language of communication, addiction, following advice on food and water intake, side effects from ART were found to be statistically associated with level of adherence among the subjects.

Conclusions: Emphasis should be given on thorough counseling of the people with HIV/AIDS so as to motivate them to take medication as advised and to maintain adequate adherence level of therapy improving their general well-being.

Keywords: Anti-retroviral therapy, Adherence level, Determinants, HIV/AIDS

INTRODUCTION

Infection by the Human Immunodeficiency Virus (HIV), a retrovirus, leads to human immune system destruction with functional impairment. In its early stages, the disease is asymptomatic. However, with further progression, the immune system becomes weaker, and the person becomes more susceptible to opportunistic infections. The most advanced stage of HIV infection is known as Acquired Immunodeficiency Syndrome (AIDS), which takes about 10-15 years for development following the infection.¹ There were estimated 2.1 million new HIV infections worldwide, giving a total of 36.7 million people living with HIV (PLHIV) in 2015. The number of PLHIV on anti-retroviral therapy (ART) in 2015 was 17 million.² The estimated number of PLHIV in India was 20.89 lakh in 2012. The adult (15-49 years) prevalence of HIV has continued its steady decline from 0.41% in 2001 to 0.27% in 2011.³ But still, India is the
third highest contributor of PLHIV after South Africa and Nigeria.4

Introduction of combination therapy with new classes of drugs during 1995-96 was the milestone in the history of HIV/AIDS.5 Free ART was introduced in India in 1st April 2004. Initially, free ART was provided at the ART centres of six high prevalence states Andhra Pradesh, Karnataka, Maharashtra, Tamil Nadu, Manipur and Nagaland, and also in National capital territory of Delhi.6 The different classes of ARVs act at different stages of HIV life cycle. During the period when this study was conducted, the most common regimen used was a fixed drug combination of two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) and one Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI). Of the two NRTIs, one was Lamivudine (3TC), the other being one among Zidovudine (AZT), Stavudine (d4T) and Tenofovir (actually a Nucleoside Reverse Transcriptase Inhibitor or NRTI). Stavudine were being phased out gradually. The NNRTI used was either Nevirapine (ETV) or Efavirenz (EFV).7 The primary goals of ART include maximal and durable reduction in plasma viral load, restoration of immunological functions which ultimately aim at prolongation of life and improvement in quality of life. Adequate adherence (i.e. more than 95% adherence) can lead to rise in a patient’s body weight, CD4 count; general well-being is also improved and there is decreased risk of opportunistic infections. Adherence to ART depends on the characteristics of the patient, family and social support, psycho-social factors and also on patient-provider relationship. In this context, this study was conducted with the objective of describing the factors associated with adherence pattern to ongoing ART regimens in adults with HIV/AIDS in a tertiary hospital setting, namely R. G. Kar Medical College and Hospital (RGKMC), Kolkata, West Bengal, India.

METHODS

An observational, descriptive cross-sectional study on the adults receiving treatment at the ART centre of R. G. Kar Medical College, Kolkata, was conducted from August 2013 to July 2014. Patients aged 15 years or above, who had given consent and received antiretroviral therapy for at least one year before the day of interview were considered as the study subjects. Sampling frame consists of the treatment cards of the patients aged 15 years or above, registered, alive and on ART till 31st July 2012 (i.e. one year before the first date of interview), as obtained from the register at ART Centre of R.G. Kar Medical College, Kolkata.

Different studies have shown difference in prevalence of adequate (≥95%) adherence to antiretroviral therapy in India. A study conducted by Shah et al. showed 73% patients maintained adequate adherence considering 95% adherence as the cut off value for adequate adherence as mentioned by WHO.8 So, prevalence of patients with adequate adherence was considered to be 73%. Using the formula, minimum sample size \( n = \frac{z^2 \times p \times (100-p)}{d^2} \) [where, \( n \) = minimum sample size; \( z \) = 1.96 for 95% confidence interval (CI); \( p \) = prevalence of patients with adequate (≥95%) adherence; \( d \) = absolute precision, taken as 5%], the sample size \( n \), as obtained, was 303. The sample size \( n = 303 \) was more than 10% of the total population \( N= 2021 \). So, using the finite population correction, the corrected minimum sample size \( n \) was \( N^2/n(N+n) \) i.e. 264. Simple random sampling had been used on everyday visit to ART Centre for data collection. Sampling was done till the last week of the last month of the interview and a total of 279 patients were interviewed for the study. Each study subject was briefed about the purpose of the study. The subjects were assured of confidentiality and an informed consent was sought from each of them before initiating the interview. Permission was obtained from Ethical Committee of R.G. Kar medical College and hospital, and West Bengal State AIDS Prevention and Control Society (WBSAP&CS).

The ART adherence for a patient was measured at every monthly visit using the following formula.

\[
\text{No. of tablets the patient had consumed in a given duration} \times 100\%
\]

\[
\text{Adherence} = \frac{\text{No. of tablets the patient should have consumed in the same duration}}{\text{No. of tablets the patient had consumed in a given duration}} \times 100\%
\]

The adherence levels were classified as adequate (≥95%) and inadequate or poor (<95%).

For measuring the adherence level in last one year, the minimum level of adherence in last twelve months was considered, rather than taking the average value, as it would ‘dilute’ the result. For example, if a patient’s adherence level in last three months were 100%, 99% and 92%, then the minimum value 92% was taken as the adherence level of the patient, which comes under inadequate (<95%) adherence, but the average value of 97% will rather ‘dilute’ the situation as it will show an adequate level of adherence.

Data were collected by review of treatment card of individual patients, followed by interview using a pretested schedule. Information regarding socio-demographic profile, disease profile, treatment details, addiction etc. was also obtained. IBM SPSS (version 20.0) was used for appropriate statistical analysis. Binary logistic regression, Chi square test, multiple logistic regression were done to find out association between variables.

RESULTS

The study conducted on the patients receiving at least one year of treatment at the ART centre of RGKMC reveals 262 (93.9%) subjects had adequate (≥95%) adherence in
last one year (Table 1). Table 2 depicts different socio-demographic factor and their association with level of adherence. Binary logistic regression doesn’t show any association between level of adherence and variables like age, gender, religion, marital status, socioeconomic status and level of education. But statistically significant association was found between language of communication at the ART centre and adherence level, showing people who communicated in Hindi were at higher risk to have inadequate adherence level, as compared to those who communicated in Bengali (P = 0.034). Table 3 reveals compared to subjects who were employed at the time of study, those without employment were at 2.085 times higher risk of having low adherence level (95% C.I. 1.043–7.544) and the finding was statistically significant (P= 0.041). Statistical association was also found between adherence level and monthly income (Chi square value = 6.527, df = 1, P = 0.011). No significant association was found between level of adherence and stage of HIV infection at the time of first visit and also the rise of CD4 count since the beginning of therapy. But binary logistic regression shows compared to patients in stage 1 of HIV infection on last visit, those who are in stage 2 had 4.654 times higher chance and those in stage 3 had 5.762 times higher chance of having inadequate adherence in last one year and these values were statistically significant (P values 0.029 and 0.04 respectively) (Table 4).

Table 1: Distribution of study subjects according to level of adherence in last one year (N=279).

| Level of adherence | Number of patients | Percentage |
|--------------------|--------------------|------------|
| Adequate           | 262                | 93.9       |
| Inadequate         | 17                 | 6.1        |
| Total              | 279                | 100.0      |

Table 2: Association between adherence level and socio-demographic profile (N=279).

| Variables                              | Adequate | Inadequate | Unadjusted OR | 95% C.I. | P value |
|----------------------------------------|----------|------------|---------------|----------|---------|
| **Age group (years)**                  |          |            |               |          |         |
| 15-24                                  | 10       | 1          |               |          | 0.471   |
| 25-34                                  | 99       | 7          | 0.707         | 0.079–6.343 | 0.757   |
| 35-44                                  | 112      | 4          | 0.357         | 0.036–3.508 | 0.377   |
| 45-54                                  | 36       | 4          | 1.111         | 0.111–11.089 | 0.928   |
| 55-64                                  | 5        | 1          | 2.0           | 0.102–39.079 | 0.648   |
| **Sex**                                |          |            |               |          |         |
| Male                                   | 187      | 11         |               |          | 0.559   |
| Female                                 | 75       | 6          | 1.36          | 0.458–3.810 | 0.559   |
| **Religion**                           |          |            |               |          |         |
| Hindu                                  | 231      | 14         |               |          | .0481   |
| Muslim                                 | 31       | 3          | 0.626         | 0.170–2.303 | .0481   |
| **Marital status**                     |          |            |               |          |         |
| Single                                 | 42       | 3          |               |          | 0.985   |
| Married                                | 192      | 12         | 1.214         | 0.118–12.508 | 0.870   |
| Divorced/separated                     | 11       | 1          | 1.062         | 0.130–8.672 | 0.955   |
| Widowed                                | 17       | 1          | 1.545         | 0.087–27.358 | 0.767   |
| **Language of communication***         |          |            |               |          |         |
| Bengali                                | 223      | 11         |               |          | 0.034*  |
| Hindi                                  | 39       | 6          | 3.119         | 1.090–8.924 | 0.034*  |
| **Socio-economic status (Modified B. G. Prasad’s scale, 2013)** | | | | | |
| I                                      | 12       | 1          |               |          | 0.574   |
| II                                     | 35       | 1          | 0.343         | 0.020–5.917 | 0.461   |
| III                                    | 47       | 1          | 0.255         | 0.015–4.385 | 0.347   |
| IV                                     | 108      | 10         | 1.111         | 0.131–9.448 | 0.923   |
| V                                      | 60       | 4          | 0.800         | 0.082–7.800 | 0.848   |
| **Level of education**                 |          |            |               |          |         |
| Illiterate                             | 80       | 6          | 121160675.7   | 0.000– | 0.998   |
| Primary                                | 82       | 6          | 118205537.3   | 0.000– | 0.998   |
| Middle school                          | 48       | 1          | 33655743.26   | 0.000– | 0.998   |
| Secondary                              | 13       | 2          | 248534719.4   | 0.000– | 0.998   |
| Higher secondary                       | 18       | 2          | 179497297.4   | 0.000– | 0.736   |
| College and above                      | 21       | 0          |               |          |         |
Table 3: Association between adherence level and employment status (N=279).

| Variables                 | Adherence | Test results |
|---------------------------|-----------|--------------|
|                           | Adequate  | Inadequate   |
| **Employment*             |           |              |
| Employed                  | 187       | 8            |
| Unemployed                | 75        | 9            |
| **Monthly income*         |           |              |
| <5000 INR                 | 167       | 16           |
| ≥5000 INR                 | 95        | 1            |

Chi square value = 6.527  
df = 1, P = 0.011*  

# includes subjects with no employment, i.e. zero income.

Table 4: Association between adherence level and disease profile (N=279).

| Variables                           | Adherence | Unadjusted OR | 95% C.I. | P value |
|-------------------------------------|-----------|---------------|----------|---------|
|                                     | Adequate  | Inadequate    |          |         |
| **Stage of HIV infection in first visit** |           |               |          |         |
| Stage 1                             | 82        | 5             | 0.331    | 0.62    |
| Stage 2                             | 99        | 2             | 1.587    | 0.194   |
| Stage 3                             | 62        | 6             | 3.453    | 0.084   |
| Stage 4                             | 19        | 4             | 1.800    | 0.533   |
| **Stage of HIV infection in last visit** |           |               |          |         |
| Stage 1                             | 242       | 12            | 4.654    | 0.029   |
| Stage 2                             | 13        | 3             | 1.367    | 0.791   |
| Stage 3                             | 7         | 2             | 5.762    | 0.040   |
| **Increase in CD4 count since beginning of ART** |           |               |          |         |
| Yes                                 | 251       | 17            | 0.000    | 0.999   |
| No                                  | 11        | 0             | 0.000    |         |

Table 5: Association between adherence level and treatment profile (N=279).

| Variables                          | Adherence | Unadjusted OR | 95% C.I. | P value |
|------------------------------------|-----------|---------------|----------|---------|
|                                     | Adequate  | Inadequate    |          |         |
| **Duration of treatment (in years)** |           |               |          |         |
| 1-2                                | 82        | 3             | 2.362    | 0.874   |
| 2-3                                | 81        | 7             | 0.590 – 9.454 | 0.224   |
| 3-4                                | 58        | 5             | 0.542 – 10.252 | 0.253   |
| 4-5                                | 20        | 1             | 0.135 – 13.842 | 0.791   |
| 5-6                                | 8         | 0             | 0.000    | 0.999   |
| ≥6                                 | 13        | 2             | 0.203 – 21.774 | 0.533   |
| **Ongoing regimen*                 |           |               |          |         |
| ZLN                                | 126       | 7             | 1.946    | 0.915   |
| ZLE                                | 37        | 4             | 0.540 – 7.013 | 0.309   |
| SLN                                | 22        | 1             | 0.096 – 6.980 | 0.854   |
| SLE                                | 9         | 0             | 0.000    | 0.999   |
| TLN                                | 48        | 3             | 0.279 – 4.529 | 0.868   |
| TLE                                | 20        | 2             | 0.349 – 9.286 | 0.483   |
| **Reminder of medication*           |           |               |          |         |
| Spouse                             | 148       | 9             | 0.000    | 0.165   |
| Parents                            | 6         | 0             | 0.000    | 0.999   |
| Children                           | 3         | 2             | 10.963   | 0.014   |
| Others                             | 35        | 2             | 0.194 – 4.543 | 0.938   |
| Self                               | 70        | 4             | 0.280 – 3.156 | 0.920   |
| **Knowledge about duration of treatment** |           |               |          |         |
| Correct                            | 165       | 13            | 0.865    | 0.395   |
| Incorrect                          | 44        | 3             | 0.239    | 0.827   |
| No knowledge                       | 53        | 1             | 0.031 – 1.874 | 0.173   |

# Z = Zidovudine, S = Stavudine, T = Tenofovir, L = Lamivudine, N = Nevirapine, E = Efavirenz.

P value
Table 6: Association between adherence level and factors related to treatment (N=279).

| Variables                                      | Adherence | Test result |
|------------------------------------------------|-----------|-------------|
| Previous change in regimen since stating ART | Adequate  | Inadequate  |
| Yes                                            | 179       | 15          | Chi square value = 2.989 |
| No                                             | 83        | 2           | df = 1, P = 0.084 |
| Knowledge about side effect from ART*          |           |             |
| Correct                                        | 114       | 12          | Unadjusted OR = 0.121 |
| Incorrect                                      | 146       | 5           | 0.325 |
| No knowledge                                   | 2         | 0           | 0.000 |
| Perceived side effect*                         |           |             |
| Yes                                            | 73        | 11          | Chi square value = 10.298 |
| No                                             | 189       | 6           | df = 1, P = 0.01* |

Table 5 describes different aspects of treatment profiles. Ongoing regimen, duration of treatment and knowledge about duration of treatment do not have any significant association with level of treatment adherence in last one year. But compared to the subjects who were reminded to take medicines by their spouses, those who were reminded by their offspring were at 10.963 times higher risk of having inadequate adherence (P=0.014).

Table 7: Association between adherence level and lifestyle (N=279).

| Variables                                      | Adherence | Unadjusted OR | 95% C.I. | P value |
|------------------------------------------------|-----------|---------------|----------|---------|
| Addiction to alcohol*                          | Adequate  |               |          |         |
| Current drinker                                | 10        | 3             | 6.480    | 1.539 – 27.283 | 0.011* |
| Former drinker                                 | 36        | 4             | 2.400    | 0.714 – 8.065 | 0.157 |
| Lifetime abstainer                             | 216       | 10            |          |         |
| Addiction to smoking                           |           |               |          |         |
| Current smoker                                 | 56        | 5             | 0.839    | 0.218 – 3.227 | 0.721 |
| Former smoker                                  | 45        | 3             | 1.339    | 0.304 – 5.908 | 0.798 |
| Never smoker                                   | 161       | 9             |          |         |
| Other addiction*                               |           |               |          |         |
| Present                                        | 24        | 5             | 4.132    | 1.342 – 12.722 | 0.013* |
| Absent                                         | 238       | 12            |          |         |
| Follows doctor’s advice on food intake*        |           |               |          |         |
| Always                                         | 71        | 2             |          |         |
| Sometimes                                      | 163       | 9             | 1.960    | 0.413 – 9.303 | 0.397 |
| Never                                          | 28        | 6             | 7.607    | 1.448 – 39.968 | 0.017* |
| Follows doctor’s advice on water intake*       |           |               |          |         |
| Always                                         | 71        | 2             |          |         |
| Sometimes                                      | 150       | 8             | 1.893    | 0.392 – 9.146 | 0.427 |
| Never                                          | 41        | 7             | 6.061    | 1.202 – 30.560 | 0.029* |

Table 7 shows different lifestyles among the subjects and their association with adherence level. Compared to the lifetime abstainers, the current drinker were at higher risk of having inadequate adherence (unadjusted OR = 6.48, P = 0.11). Also, subjects with any addiction (other than alcohol and smoking) were at 4.132 times higher risk to develop inadequate adherence (P = 0.013). Those subjects, who never followed doctor’s advice on food intake were at 7.607 times higher risk having inadequate adherence (P = 0.017). Similar finding was seen among
subjects who never followed doctor’s advice on water intake (unadjusted OR = 6.061, P = 0.029).

Different variables were found to be associated with adherence level of the study subjects in last one year and the association was found to be statistically significant. The variables were put into Multiple Logistic Regression (MLR) model by forward method, until the variables fit the model and then the analysis was done. Even though HIV infection on latest visit was found to be significantly associated on binary logistic regression, the infection status on registration (or first visit) was included into the MLR model. After putting the variables in MLR model, HIV infection of stage 4 at first visit, current employment status, perceived side effects form ART, regular alcohol drinking and having addictions other than alcohol or smoking were found to be of higher risk of having inadequate adherence (Table 8).

Table 8: Multiple logistic regression showing association of different variables with adherence level of study subjects in last one year (N=279).

| Variables                      | Adjusted OR | 95% C.L       | P value |
|--------------------------------|-------------|---------------|---------|
| Language of communication      |             |               |         |
| Bengali                        | 3.583       | 0.796 – 16.128| 0.096   |
| Hindi                          |             |               |         |
| HIV stage at first visit       |             |               |         |
| HIV stage 1                    | 0.072       | 0.006 - 920   | 0.043*  |
| HIV stage 2                    | 1.792       | 0.362 – 8.854 | 0.474   |
| HIV stage 3                    | 7.011       | 1.128 – 43.591| 0.037*  |
| HIV stage 4                    |             |               |         |
| Employment                     |             |               |         |
| Yes                            | 6.869       | 1.320 - 35.750| 0.022*  |
| No                             |             |               |         |
| Monthly income                 |             |               |         |
| <5000 INR                      | 2.340       | 0.224 - 24.428| 0.478   |
| ≥5000 INR                      |             |               |         |
| Perceived side-effects         |             |               |         |
| Yes                            | 7.927       | 2.051- 30.638 | 0.003*  |
| No                             |             |               |         |
| Follows doctor’s advice on food intake* | | | |
| Always                         | 1.301       | 0.175 – 9.658 | 0.797   |
| Sometimes                      | 2.164       | 0.079 – 59.369| 0.648   |
| Never                          |             |               |         |
| Follows doctor’s advice on water intake* | | | |
| Always                         | 4.977       | 0.489 – 50.703| 0.175   |
| Sometimes                      | 2.164       | 0.086 – 67.028| 0.605   |
| Never                          |             |               |         |
| Alcohol addiction              |             |               |         |
| Regular                        | 16.790      | 1.441- 195.571| 0.023*  |
| Social                         | 5.641       | 1.121 – 28.375| 0.024*  |
| Never                          |             |               | 0.036   |
| Other Addiction                |             |               |         |
| Present                        | 7.382       | 1.077 - 50.579| 0.042*  |
| Absent                         |             |               |         |

Nagelkerke R square value 0.443. Variables fit the model.

DISCUSSION

Our study shows age of the patients had no significant association with adherence level of the patients. This finding was also in accordance with the study of Sanjay Sinha et al and Sarna et al.9,10 Though the proportion of patients with adequate adherence is higher among males than among females, this difference was not statistically significant. This finding is also in accordance with the study of Sanjay Sinha et al and Sarna et al.9,10 In this study, marital status was not found to have association with adequacy of adherence. Similarly no such association was found in the study by Vivek Lal et al.11 Our study also revealed the unemployed patients are more like to be inadequately adherent to ART compared to those who were employed at the time of interview (OR = 2.805, 95% CI = 1.043-7.544, P = 0.041). Employment status was also found to be a factor determining...
adherence level, when put in MLR model. Our study shows patients who contributes financially to their family with less than Rs.5000/- per month (this include the unemployed patients as well), were more likely to have inadequate adherence (Chi square value = 6.527, df =1, P= 0.011). Carol et al., in their study, conducted in a county hospital in US, found no significant association between monthly income and adherence of the patients. But this can probably be attributed to the economic difference between these two countries. It should be considered that people with lower socio-economic status, especially those who are daily wagers, not only have to miss their work for collecting medicine on scheduled date, but also have to pay the transport cost and other necessary costs out of their own pockets, hence may be reluctant to come to ART centre, RGKCMCH to collect the medicines. Another interesting finding was, compared to those people who communicate in Bengali, those who use Hindi for communication were at 3.119 times higher risk of having inadequate adherence, and this finding was statistically significant (P= 0.034). This prompts to identify any communication gap between the beneficiaries and the service providers.

Alcohol addiction was found to have significant role in adherence level in study subjects. Compared to lifetime abstainers those who were current drinkers were at higher risk of having inadequate adherence (OR= 6.480, 95% CI= 1.539-27.283, P= 0.11). Though the study by Sarna et al didn’t show any significant association between alcohol intake in last 30 days with adherence, study by Sanjay Sinha et al shows alcohol intake of once or more in last 30 days has higher risk of having inadequate adherence (OR= 6.39, 95% CI= 4.15- 9.84, P= 0.00). Both alcohol addiction and addiction other than alcohol or smoking were found to be factors determining adherence level, when put in MLR model Subjects who do not follow doctor’s advice on food and water intake were also found to have higher risk of having inadequate adherence. This reflects the attitude towards the life from the subjects’ perspective as these are the people to be less compliant to the therapy, leading to short term and long term effects on treatment outcome (Table 7). Perceived side effect of ART was also found to be a factor determining adherence level, when put in MLR model. In case of any adverse reaction which were perceived by the study subjects as side-effects from the ART medications, may lead the patients to discontinue the drugs for once or more and it results in fall in percentage adherence. In the study by Sarna et al presence of moderate to severe side-effects were found to have higher risk of having inadequate adherence compared to those with none to mild side-effects (OR= 5.40, 95% CI= 2.47-11.81, P= 0.000).

CONCLUSION

The study conducted at the ART centre of RGKCMCH shows association of different factors with level of treatment adherence among subjects receiving ART for at least one year before the study. Among different factors, employment status was found to be associated with level of adherence, also, people earning Rs.5000/- or more were at lower risk of having low adherence level (<95%). A good communication skill, along with proper counseling services by the medical and non-medical staffs of ART centre, is desirable, as subjects communicating in Hindi were having inadequate adherence, thus pointing out probable communication gap between the beneficiaries and the service providers. Subjects having addiction of alcohol and other substances (other than smoking), and also those who do not follow doctor’s advice on food and water intake were found to be having inadequate adherence. Thorough counseling on the disease and its treatment, importance of regular, timely and lifelong therapy and problems due to frequent non-compliance to therapy should be provided to the subjects so as to motivate them to take medications as advised and maintain high adherence level for improved survival and quality of life among the PLHIVs.

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