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Manuscript title

Adherence to highly active antiretroviral therapy among people living with HIV associated with high-risk behaviours and clinical characteristics: results from a cross-sectional study in Vietnam

Running head

HAART adherence among PLHIV in Vietnam

Abstract:

Although Vietnam has promoted the utilization of highly active antiretroviral therapy (HAART) toward HIV elimination targets, it has remained under-investigated. We aimed to describe high-risk behaviours and clinical characteristics by adherence status and to identify the factors associated with non-adherence. We included 426 people living with HIV (PLWH) currently or previously involved in HAART. Most participants were men (75.4%), young (33.63 years), with low income and low education levels. Non-adherent PLWH (11.5%) were more likely to have larger number of sex partners (p-value=0.053), sex without condom use (p-value=0.007), and not receive result at hospital or voluntary test center (p-value=0.001). Multiple logistic regression analysis showed that demographic (education levels), sexual risk behaviours (multiple sex partners, sex without using condom), and clinical characteristics (time and facility at first time received HIV positive result) were associated with HAART non-adherence. There are differences in associated factors between women (education levels and place of HIV testing) and men (multiple sex partners). Gender-specific programs, changing risky behaviours and reducing harms among PLWH may benefit adherence. We highlight the need to improve the quantity and quality of HIV/AIDS services in Vietnam, especially in pre- and post-test counselling, to achieve better HAART adherence, toward ending AIDS in 2030.

Keywords: non-adherence, HAART, people living with HIV, associated factors, Vietnam	

1. Introduction

HIV/AIDS is a global public health problem that affects people in the most productive stage of life. Highly active antiretroviral therapy (HAART) has contributed to prolonging life expectancy and improving quality of life of people living with HIV (PLWH), and has become a key component of the HIV response.¹ The Joint United Nations Programme on HIV/AIDS (UNAIDS) introduced the 90-90-90 targets for HAART programs in 2014. These global targets call for 90% of PLWH to know their HIV status, 81% to be on HAART, and 72% to be virally suppressed by 2020.² The World Health Organization (WHO) considers adherence to HAART to be a central part of the Treatment as Prevention (TasP) strategy, a global approach to control the HIV epidemic.^{3,4} Nevertheless, UNAIDS projects that the global 2020 target will not be achieved and the HIV elimination goal will be delayed by 10 years or more due to unequal progress within and between countries.^{5,6}

Vietnam has a stable HIV epidemic concentrated in some high-risk groups of people who inject drugs (PWID), sex workers (SWs), and men who have sex with men (MSM).^{7,8} There were approximately 230000 PLWH in 2018, with 5000 people dying annually due to AIDS and 5200 newly infected cases.⁹ Committing to achieving the UNAIDS targets, Vietnam had promoted WHO's initiative Treatment 2.0 and issued new guidelines for diagnosis and treatment of HIV/AIDS to increase the uptake of HAART.¹⁰ By 2019, 160000 PLWH were on HAART, which accounted for 70% of the total number of PLWH.⁹ In the context of resource-restricted settings, adherence is not only crucial for improving HAART coverage and ensuring treatment effectiveness but is also needed for preventing drug resistance and avoiding the cost of moving to second and third line HAART. However, a recent study showed that 25% of people receiving ART reported non-optimal adherence, and missed 25% of doses in the last 7 days.¹¹ HIV/AIDS

prevention and control in Vietnam is facing several challenges with inequalities in receiving health services, ^{12,13} thus more endeavours are needed in progress toward HIV elimination in this low- and middle-income country. ¹⁴

Since HAART non-adherence is one of the most serious challenges to the success of HIV treatment, much has been done to identify its associated factors. Prior studies revealed that depression, stigma, drug side effects, forgetfulness, marital status, and inequalities in socioeconomic conditions were associated with HAART non-adherence in Vietnam. However, quality of the decentralized HAART delivery services needs to be routinely evaluated for its impact on HAART utilization. Additionally, context-specific knowledge regarding high-risk behaviours and clinical and health service characteristics is still lacking in Vietnam. This scientific-based information is of great interest to policymakers and program managers to make appropriate public health plans and practice decisions. In this study, we determined the high-risk behaviours, clinical and healthcare service characteristics of PLWH on HAART by their adherence status and identified the factors associated with HAART non-adherence in Vietnam.

2. Methods

Study design: We used data from a cross-sectional study of people living with HIV (PLWH) in Vietnam in the provinces of Hanoi and Nghe An in 2017 (the capital city and the largest province of Vietnam's central coast regions). This survey was used a convenience sampling method to achieve the speedy, easy, readily available, and cost effective. ^{16,17}

Participant recruitment: We recruited participants using HIV/AIDS case reporting procedures of the Vietnam Authority of HIV/AIDS Control (VAAC). In Vietnam, HIV screening tests are currently performed in three main domains, including hospital systems, Voluntary Counselling and Testing (VCT) centers, and other settings such as private clinics or prison facilities. In contrast, the confirmation tests are conducted only at provincial centers of HIV/AIDS prevention and control. They summarize all HIV positive results and report them to VAAC as provincial monthly reports. The research team used those reports to selected facilities in Hanoi and Nghe An in 2017. A total of 440 adult clients (older than 15 years old) with confirmed HIV-positive results were approached for this study. Finally, information of 426 PLWH (response rate = 97%), who were currently or previously involved in HAART, was used for analysis. This sample size is considered as appropriate for multiple regression analyses with less than 30 covariates according to Cohen et al.¹⁸

Measured information: We measured HAART adherence using participants' self-reported compliance with prescribed medications in the 30 days before the interview.¹⁹ The adherence questions were coded as a dichotomised variable with "adherence to HAART" defined as intake of greater than or equal to 90% prescribed doses, versus "non-adherence to HAART" for less than 90%. Participants' demographic information (i.e., gender, age, education level, income, marital situation, and HIV transmission mode) was collected. We asked clients for their sexual risk

behaviours encompassing the number of partners over the last one year, sexual history (having sex with or without a condom), and ever forced to have sex. We asked participants for information about the history of using drugs or stimulants, the age at first time use of use, injection of any drug, needle sharing, and the number of shared partners over the last six months. We finally asked participants for their clinical characteristics (i.e., history of sexually transmitted diseases, recently successful treatments, time and the facility since receiving first HIV positive results, recent treatment status and regimen, and the results of initial CD4 test).

Statistical analysis: We performed univariate analysis including descriptive and inferential methods for demographic information, high-risk behaviours, and clinical characteristics between HAART non-adherent and adherent groups. We applied the Student's t-test for continuous variables, Pearson's chi-squared and Fisher's Exact test for categorical variables. To examine the key determinants of HAART non-adherence behaviours, we used multivariable logistic regression models. Since there are differences in high-risk behaviours between genders, we conducted models separately for men and women along with an overall model. Associations were measured by the estimation of adjusted odds ratios (aORs) and 95% confidence intervals (95% CI). We selected predictors for the multivariate model based on our prior knowledge about relationships between variables and outcomes, results from univariate analysis, and our specific research interests. Finally reduced multivariable models were developed by using forward stepwise variable selection based on the smallest Akaike Information Criterion. All analyses were conducted using R Version 4.0.2.

Ethics Statement: This study used data from the survey of people living with HIV (PLWH) in Vietnam of the Center for Community Health Research and Development. The United States Agency for International Development (USAID) approved this survey's ethics with IRB

approval number IRB00006556. All the participants were provided verbal consents, information on the study's objectives and methods, and anonymous and opt-out rights. Additionally, identical information of participants was not collected.

3. Results

Table 1 presents the demographic characteristics of 426 PLWH separately for the non-adherent (11.5%) and adherent group (88.5%). The majority of participants were men (75.4%), Kinh ethnicity (85.2%), quite young (average of 33.63 years old), and with education levels of secondary school or lower (71.9%). They mostly were living with spouses (50.0%), had unstable jobs and casual employment (65.3%), with an average income of 3.9 million dong (approximately 170 US dollars). The HIV transmission modes were reported mainly as same or opposite sex sexual activity. Table 1 shows a statistically significant difference only in monthly income (p-value=0.078) between non-adherent and adherent groups.

The high-risk behaviours (including sexual and drug injection-related risk behaviours) of participants by HAART adherence status are shown in Table 2. There was a significant difference in having multiple sex partners between adherence status (p-value=0.053), with 26.1% of 426 PLWH reporting multiple sex partners with two or more partners in the last 12 months. Among those having at least one sex partner (n=383), 85.1% reported unsafe sexual behaviour without using a condom with a significant difference (p-value=0.007) between adherence status. Drug injection behaviours were reported in 157 participants (36.9%), and the majority of those who had ever used drugs or stimulants were men (156/157) starting at the average age of 21.9 years old. Among them, nearly half (49.4%) had injected drugs with 48.1% recently sharing needles.

The clinical characteristics of PLWH by adherence status are described in Table 3. Among 383 sexually active participants, 15.1% reported having a history of sexually transmitted infections (STIs), and only 87.9% of those 51 PLWH stated that the treatment was successful. Additionally, 42.6% of those 383 people knew their partner's HIV status with 71.8% reported as serodiscordant couples, with no difference by adherence status. Nearly half (46.2%) of 426 PLWH reported the

time since their last HIV test of 3 to 12 months, and most of the respondents (78.4%) had taken voluntary HIV testing at that time, with statistically significant differences between adherence status.

Table 4 presents multivariable logistic regression models for factors associated with HAART non-adherence. The overall model shows that demographic (education levels), sexual risk behaviours (multiple sex partners, sex without using condom), and clinical characteristics (time and facility since receiving the first HIV positive result) were associated with non-adherence to HAART. Factors associated with non-adherence in women include education levels and place of HIV testing. In men, multiple sex partners were associated with non-adherence. Time since the first HIV positive result was significant in both women (p-values of 0.046 and 0.002) and men (p-values of 0.003 and <0.001).

4. Discussion

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The present study examined the high-risk behaviours and clinical characteristics of PLWH on HAART and the factors associated with non-adherence to HAART. This study's participants are comparable with previous studies of PLWH in Vietnam in some demographic characteristics (e.g., age, gender distribution), and socio-economic status (e.g., educational level, income).²⁰ The distribution of HIV transmission mode in this study is highly similar to the current HIV transmission pattern in Vietnam.²¹ Overall, 11.5% of our sample reported non-adherence, which is quite high. If this result were generalizable to the current number of PLWH in Vietnam, ²¹ nearly 24.380 patients can be expected to be non-adherent. These figures should deserve close attention among AIDS control policymakers, programmers and practitioners. More importantly, we found that high-risk behaviours are more common among non-adherent PLWH. If these trends were to continue without policy adaptation, the transmission of HIV/AIDS would be expected to continue. Our results highlight the critical role of clinical factors and health services, especially the time and facility of the first HIV test at which participants received a positive result, in nonadherence to HAART among PLWH in Vietnam. In particular, time since the first HIV positive test is a similarly associated factor in both men and women. There are several possible explanations for this, such as a decline over time in awareness of HAART's effectiveness and adherence, drugresistance, and other difficulties in taking medicine regularly.²² Furthermore, HIV testing context and facilities are the notable factor in HAART non-adherence among PLWH and particularly women. This is understandable as voluntary testing is recognized as a cost-effective strategy in reducing high-risk behaviours of HIV transmission and ensuring HAART adherence in low- and middle-income countries such as Vietnam.²³ Our result indicates that women, who received HIV positive result outside of mainstream health services (i.e., hospitals, VCT), were more likely to be

non-adherent to HAART. This finding suggests the vital role of HIV counsellors in providing HIV service packages, including testing, counselling, referral to treatment, and adherence support.²⁴ Knowing that adherence counselling is essential in increasing treatment effectiveness and reducing drug resistance, findings from our study emphasise the need to strengthen the counselling procedure at the HIV testing facilities.²⁵ Vietnam has gained specific achievements in healthcare in general and HIV and AIDS prevention and control in particular by reforming health systems and policies.²⁶ Given this, shortages in both quantity and quality of staff may have a significant impact on the quality of HIV services and may deserve more attention.²⁷

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Results from multivariable logistic regression models suggest differences between men and women in factors associated with HAART non-adherence, which are comparable with previous studies in other countries.²⁸ While socioeconomic factors (education levels) had a considerable impact on HAART non-adherence among women, sexual risk behaviours (number of sex partners) substantially affected men. These findings suggest that future HIV/AIDS interventions and programs should be explicitly and separately designed for women and men to achieve higher efficiency. Education has been shown to have an association with non-adherence to HAART among women, and is recommended by UNAIDS as a critical target for improving women's HIV/AIDS outcomes.²⁹ Our results confirm this, and suggest overconfidence and insufficient knowledge of HIV/AIDS even among highly educated women. More efforts are still needed in both the short term by implementations of health education strategies (e.g., integrating HIV/AIDS education into school, HIV/AIDS communication campaigns via the Internet and social networks) and long term with a focus on women's empowerment and gender equality.³⁰ On the other hand, our multivariable analysis shows a positive association between having multiple sex partners and HAART non-adherence among men, which is consistent with previous studies investigating sexual risk behaviours.³¹ Hence, our results suggest the co-existence of non-adherence and other high-risk behaviours among men, which may amplify the risk of HIV transmission and present an immense challenge for future HIV and AIDS programs and interventions targeting men.³² The lack of association between having ever experienced an STI and non-adherence among MWLH is also consistent with other studies in that adherence was not associated with the presence or absence of coinfections.³³

Among our sample, the PLWH who participated in treatment reported a higher prevalence (85.1%) of having sex without using a condom in the last sexual intercourse than previous results (71%) in other regions.³⁴ Also, the majority of those knowing the HIV status of sex partners (71.8%) had HIV negative partners. Those results suggest a high transmission risk among those serodiscordant couples. This may partially reflect the inefficiency of behaviour change communication for harm reduction in HIV/AIDS facilities in Vietnam. The prevalence of 6.9% untreated STIs, which can heighten the risk of HIV transmission, indicate that the WHO's recommendation of screening STIs for all PLWH is still not fully achieved in Vietnam.³⁵ As such, we argue the need for appropriate interventions for STIs and more effective counselling in harm reduction programs.

To the best of our knowledge, this is the first study to examine the association between high-risk behaviours and clinical characteristics with HAART non-adherence among PLWH in Vietnam. We recognise several limitations in the present study. Firstly, as this study was cross-sectional, we may not ascribe causality to the associated factors in our results. Secondly, we collected and analysed the information on high-risk behaviours and HAART non-adherence based on self-reporting, which may lead to misclassification, recall bias, and intentional concealment. Thirdly, this study may have potential bias and limitations in its generalizability due to the

convenience sampling methods applied. Fourthly, other factors that might impact on HAART non-adherence among PLWH, such as stigma, discrimination, and depression, have not been investigated in this study. Forthcoming research that applies implementation science can improve the HAART adherence in both genders most effectively.

5. Conclusions

This study identified differences in high-risk behaviours and clinical and health services factors by adherence status among PLWH and suggested gender differences in factors associated with HAART non-adherence. Future HIV programs that are gender-specific and tailored-made interventions that increase socioeconomic status, change risky behaviours and reduce harms among PLWH can enhance adherence. The present study indicates the crucial importance of clinical and health services factors (the time and facility of the first HIV testing and receiving positive results) for adherence. We, therefore, call for maintaining and improving the quantity and quality of HIV services in Vietnam, especially in pre- and post-test counselling, to better achieve HAART adherence. By promoting HAART adherence programs as the centrality of WHO's Treatment as Prevention strategy, ³⁶ we believe Vietnam will have better progress toward the global targets of HIV and AIDS elimination for its people.

Conflict of interest: This research has no conflict of interest.
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Table 1: Demographic characteristics of PLWH by adherence status (n = 426)

Characteristics	Overall	Non- adherence	Adherence	P- value	
N (%)	426 (100)	49 (11.5)	377(88.5)		
Age (years), mean (sd)	33.63 (9.45)	35.22 (8.91)	33.41 (9.52)	0.208	
Gender, n (%)					
Female	105 (24.6)	15 (30.6)	90 (23.9)	0.393	
Male	321 (75.4)	34 (69.4)	287 (76.1)		
Ethnicity, n (%)					
Kinh (Vietnamese)	363 (85.2)	43 (87.8)	320 (84.9)	0.749	
Other (minority ethnicities)	63 (14.8)	6 (12.2)	57 (15.1)		
Education level, n (%)					
Complete primary school or below	114 (26.8)	8 (16.3)	106 (28.1)	0.129	
Complete secondary or high school	192 (45.1)	28 (57.1)	164 (43.5)		
Complete undergraduate or higher	120 (28.2)	13 (26.5)	107 (28.4)		
Occupation, n (%)					
Students	23 (5.4)	0 (0.0)	23 (6.1)	0.281*	
Farmers	35 (8.2)	4 (8.2)	31 (8.2)		
Workers	66 (15.5)	11 (22.4)	55 (14.6)		
Unstable casual employment	278 (65.3)	32 (65.3)	246 (65.3)		
Unemployed	24 (5.6)	2 (4.1)	22 (5.8)		
Monthly income (millions dong), mean (sd)	3.92 (2.90)	4.61 (2.41)	3.83 (2.95)	0.078	
Marital status, n (%)					
Single	132 (31.0)	12 (24.5)	120 (31.8)	0.179*	
Divorced	22 (5.2)	4 (8.2)	18 (4.8)		
Widowed	29 (6.8)	7 (14.3)	22 (5.8)		
Living with spouse	213 (50.0)	23 (46.9)	190 (50.4)		
Live with sex partner	30 (7.0)	3 (6.1)	27 (7.2)		
Mode of transmission, n (%)					
Drug injection	139 (32.6)	14 (28.6)	125 (33.2)	0.159*	
Homosexual transmission	82 (19.2)	8 (16.3)	74 (19.6)		
Heterosexual transmission	183 (43.0)	27 (55.1)	156 (41.4)		
Other (blood transfusion, occupational accidents, etc.)	22 (5.2)	0 (0.0)	22 (5.8)		

Notes: sd=standard deviation; *=exact test

		Adherence status				
Characteristics	Overall	Non- adherence	Adherence	P- value		
Sexual risk behaviours (n = 426)						
Number of sex partner (last 12 months), n (%)	426 (100)	49 (100)	377 (100)			
None	43 (10.1)	4 (8.2)	39 (10.3)	0.053		
One sex partner	272 (63.8)	25 (51.0)	247 (65.5)			
More than 2 sex partners	111 (26.1)	20 (40.8)	91 (24.1)			
Having sex without condom use (last 6 months), n (%)	383 (100)	45 (100)	338 (100)			
No	57 (14.9)	1 (2.2)	56 (16.6)	0.007		
Yes	326 (85.1)	44 (97.8)	282 (83.4)			
Being forced to have sex by partners (last 6 months), n (%)	383 (100)	45 (100)	338 (100)			
Yes	8 (2.1)	1 (2.2)	7 (2.1)	0.321		
No	362 (94.5)	41 (91.1)	321 (95.0)			
Do not answer/ Unsure of the definition of forced	13 (3.4)	3 (6.7)	10 (3.0)			
Injection risk behaviours ($n = 426$)						
Ever used drug/stimulants, n (%)	426 (100)	49 (100)	377 (100)			
No	269 (63.1)	27 (55.1)	242 (64.2)	0.27		
Yes	157 (36.9)	22 (44.9)	135 (35.8)			
Age at first used drug, mean (sd)	21.94 (4.92)	20.41 (5.53)	22.19 (4.79)	0.115		
Injected drug (last 6 months), n (%)	157 (100)	22 (100)	135 (100)			
Yes	77 (49.0)	7 (31.8)	70 (51.9)	0.108		
No	80 (51.0)	15 (68.2)	65 (48.1)			
Shared needle (last 6 months), n (%)	77 (100)	7(100)	70 (100)			
Yes	37 (48.1)	2 (28.6)	35 (50.0)	0.433		
No	40 (51.9)	5 (71.4)	35 (50.0)			
Number of needle-sharing partners (last 6 months), mean (sd)	2.11 (1.15)	1.50 (0.71)	2.14 (1.17)	0.45		

Notes: sd=standard deviation; *=exact test

		Adherence status				
Characteristics	Overall	Non- adherence	Adherence	P- value		
Experienced STIs (last 6 months), n (%)	383 (100)	45 (100)	338 (100)			
Yes	58 (15.1)	11 (24.4)	47 (13.9)	0.092		
No	311 (81.2)	34 (75.6)	277 (82.0)			
No response	14 (3.7)	0 (0.0)	14 (4.1)			
Have cured STIs, n (%)	58 (100)	11 (100)	47 (100)			
Yes	51 (87.9)	10 (90.9)	41 (87.2)	1		
No	4 (6.9)	1 (9.1)	3 (6.4)			
No response	3 (5.2)	0 (0.0)	3 (6.4)			
Know whether sex partner took a HIV test (last 6 months), n (%)	383 (100)	45 (100)	338 (100)			
No	220 (57.4)	29 (64.4)	191 (56.5)	0.339		
Yes	163 (42.6)	16 (35.6)	147 (43.5)			
HIV test results of sex partner, n (%)	163 (100)	16 (100)	147 (100)			
Negative	117 (71.8)	8 (50.0)	109 (74.1)	0.075		
Positive	46 (28.2)	8 (50.0)	38 (25.9)			
Time since received first HIV positive result, n (%)	426 (100)	49 (100)	377 (100)			
Less than 3 months	187 (43.9)	2 (4.1)	185 (49.1)	< 0.001		
From 3 to 12 months	197 (46.2)	29 (59.2)	168 (44.6)			
More than 1 year	42 (9.9)	18 (36.7)	24 (6.4)			
Facility received first HIV positive result, n (%)	426 (100)	49 (100)	377 (100)			
General hospital	67 (15.7)	4 (8.2)	63 (16.7)	0.001		
Voluntary HIV testing	334 (78.4)	36 (73.5)	298 (79.0)			
Other (prison, projects)	25 (5.9)	9 (18.4)	16 (4.2)			
Currently on ART, n (%)	426 (100)	49 (100)	377 (100)			
No	22 (5.2)	22 (44.9)	0 (0.0)	< 0.001		
Yes	404 (94.8)	27 (55.1)	377 (100.0)			
Time to involve in ART after receiving last HIV positive result, n (%)	404 (100)	27 (100)	377 (100)			

Less than 1 months	392 (97.0)	25 (92.6)	367 (97.3)	0.188
More than 1 month	12 (3.0)	2 (7.4)	10 (2.7)	
Current HAART regimen, n (%)				
First-line regimen	404 (100.0)	27 (100.0)	377 (100.0)	NA
Initial CD4 count, mean (sd)	344.22 (280.15)	281.05 (124.25)	348.46 (287.21)	0.286

Notes: sd=standard deviation; *=exact test; NA=not applicable

Table 4: Multivariable logistic regression models for HAART non-adherence behaviours in overall and separately for men and women

		Overall model			Women model			Men model		
Factors	aOR	95% CIs	P- value	aOR	95% CIs	P- value	aOR	95% CIs	P- value	
Education levels										
Primary and lower	1			1						
Secondary to high school	3.47	1.13 to 10.60	0.029	11.41	1.43 to 91.40	0.022				
Undergraduate and higher	2.93	0.86 to 10.04	0.087	4.6	0.49 to 42.83	0.18				
Having multiple sex partners										
No	1						1			
Yes	2.34	1.08 to 5.07	0.032				4.69	1.87 to 11.78	0.001	
Having sex without condom use (last 6 months)										
No	1									
Yes	13	1.53 to 110.45	0.019							
Time since received first HIV positive result										
From 3 to 12 months	1			1			1			
Less than 3 months	0.07	0.01 to 0.29	< 0.001	0.1	0.01 to 0.96	0.046	0.05	0.01 to 0.35	0.003	
More than 1 year	5.02	1.93 to 13.05	0.001	6.94	1.07 to 45.05	0.042	8.94	3.08 to 25.91	< 0.001	
Facility received first HIV positive result										
Voluntary HIV testing	1			1						
Other (prison, projects)	3.47	1.00 to 12.00	0.049	6.49	0.77 to 54.91	0.086				
General hospital	0.53	0.16 to 1.69	0.281	0.22	0.02 to 2.06	0.183				

_		Overall model			Women model	[Men model	
Factors	aOR	95% CIs	P- value	aOR	95% CIs	P- value	aOR	95% CIs	P- value
Had ever had STI in the last 6 months									
No	1						1		
Yes	2.4	0.96 to 5.99	0.062				2.62	0.88 to 7.81	0.084

Notes: aOR=adjusted Odd Ratio; CIs=Confidence Intervals

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