

# Prevalence and determinants of six-month virological failure among people living with HIV in Hubei, China: a population-based study

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## Research Article

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# Abstract

## Background

Failure to achieve virological suppression for human immunodeficiency virus (HIV) at the early time point increases the risk of subsequent treatment failure, the development of drug resistance, and inadequate immune recovery, which negatively affect both individual outcomes and population-level transmission control. Studies in China typically use one-year or longer follow-up to assess virological response, and the data specifically on six-month virological failure (VF) and its associated factors in China remain limited.

## Methods

A real-world, retrospective cohort study was conducted in Hubei province, China, among treatment-naïve people living with HIV (PLWH) who initiated ART between Feb 2022 and Jun 2025. The primary endpoint was the six-month VF rate during 2022–2025. The VF was defined as plasma HIV RNA persistently > 200 copies/mL at 24 weeks of continuous antiretroviral therapy (ART). The secondary endpoints included factors associated with six-month VF.

## Results

Among 4535 treatment-naïve PLWH, the overall six-month VF rate during 2022–2025 was 6.8%. In multivariable analysis, female (aOR = 0.65, 95% CI: 0.46–0.93,  $p = 0.017$ ), higher baseline CD4 + T lymphocyte counts (200–349 vs < 200: aOR = 0.57, 95% CI: 0.41–0.79,  $p < 0.001$ ; 350–499 vs < 200: aOR = 0.54, 95% CI: 0.35–0.85,  $p = 0.007$ ), and initiation on integrase strand transfer inhibitor (INSTI)-based regimens (aOR = 0.35, 95% CI: 0.26–0.48,  $p < 0.001$ ) were associated with lower six-month VF rates. However, high baseline HIV viral load (aOR = 1.83, 95% CI: 1.57–2.13,  $p < 0.001$ ) and infection via drug using (aOR = 9.88, 95% CI: 2.90–33.60,  $p < 0.001$ ) were associated with higher six-month VF rates.

## Conclusions

In China, to improve early treatment outcomes and long-term prognosis, it is essential to implement more refined baseline patient stratification, optimize first-line regimens, intensify follow-up strategies.

## Introduction

With advances in treatment, antiretroviral therapy (ART) has transformed human immunodeficiency virus (HIV) infection into a manageable chronic condition by achieving durable viral suppression. Widespread treatment with ART substantially reduces plasma HIV viral load (VL) and restores CD4 + T lymphocytes count (CD4 count). As a result, declines in acquired immunodeficiency syndrome (AIDS)-related

morbidity and mortality and a reduced risk of HIV transmission have improved patient survival status and quality of life. In recent years, China has made great progress in AIDS treatment and control, and the proportion of virological suppression among people living with HIV (PLWH) receiving ART has steadily increased and remains at a high level. According to a cross-sectional study from 31 provinces in China, the national HIV viral suppression rate reached 97% in 2022<sup>[1]</sup>.

Studies have shown that virological monitoring has greater sensitivity and specificity for detecting treatment failure than clinical or immunological criteria, making it a more reliable indicator<sup>[2]</sup>. Accordingly, both EACS and DHHS guidelines suggest six months an important early time point to assess whether treatment-naïve patients have achieved virological suppression and to serve as the first routine efficacy assessment<sup>[3, 4]</sup>. Similarly, the Chinese national HIV guideline defines virological suppression as HIV VL below the assay limit of detection after at least 24 weeks of consistent ART<sup>[5]</sup>. Failure to achieve virological suppression by this early time point is associated with an increased risk of long-term treatment failure, development of drug resistance, and suboptimal immune recovery, adversely affecting both individual prognosis and population-level transmission control<sup>[6]</sup>.

Factors associated with six-month virological failure (VF) include baseline patient and disease characteristics, antiretroviral regimen choice and baseline resistance, as well as adherence and socioeconomic determinants<sup>[7]</sup>. Studies in China have primarily used one year or longer as the main observation point<sup>[8, 9]</sup>. Research specifically focused on six-month VF and its influencing factors in the Chinese context remains relatively limited.

Based on a large dataset from the Center for Disease Control and Prevention (CDC) of Hubei province, our study analyzes the six-month VF rate among treatment-naïve PLWH who initiated ART between 2022 and 2025 and identifies independent risk factors for early VF. These findings will provide targeted evidence to inform first-line regimen selection, the optimization of follow-up strategies, and public health interventions for clinical practice in China.

## Methods

### Study design and participants

This real-world, retrospective cohort study was conducted among treatment-naïve PLWH in Hubei who initiated ART between Feb 2022 and Jun 2025. Patients were eligible for inclusion if they met the following criteria: (1) laboratory-confirmed HIV infection; (2) age  $\geq 18$  years; (3) available baseline and six-month HIV VL results; and (4) having received continuous ART for at least 6 months. Exclusion criteria included prior ART exposure and pregnancy or breastfeeding at baseline.

### Data collection

Patient data were obtained from the HIV electronic database of the Hubei CDC. Baseline data included demographics (sex, age, marital status, education, ethnicity) and HIV related information (plasma HIV VL, CD4 count, WHO clinical stage, transmission route, ART regimen, and opportunistic infection prophylaxis). Opportunistic infection prophylaxis with sulfamethoxazole-trimethoprim for pneumocystis jirovecii pneumonia (PJP) was also recorded.

## Study endpoints

The primary endpoints included the VF rate at 6 months. VF was defined as plasma HIV VL persistently > 200 copies/mL at 24 weeks of continuous ART following treatment initiation<sup>[5]</sup>. The secondary endpoints included risk factors associated with six-month VF.

## Statistical analysis

Normally distributed continuous variables were presented as mean  $\pm$  standard deviation (SD) and compared using the independent samples t-test or one-way analysis of variance (ANOVA). Non-normally distributed continuous variables were presented as median with interquartile range (IQR) and compared using the Mann-Whitney U test or the Kruskal-Wallis test. Categorical variables were summarized as frequencies and percentages and compared using the chi-square test or Fisher's exact test. Temporal trends of VF rates were assessed through the chi-squared for trend. Univariable and multivariable logistic regression analysis was used to determine whether each baseline demographic and clinical characteristic were associated with six-month VF. Variables with  $p < 0.10$  in univariate analysis were entered into a multivariable logistic regression model. The associations between the potential influencing factors and outcomes were presented as odds ratios (ORs) and 95% confidence intervals (CIs). All statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). A two-sided  $p$ -value  $< 0.05$  was considered statistically significant.

## Results

### Characteristics of study participants

From Feb 2022 to Jun 2025, a total of 10,563 newly treated PLWH were identified. By the end of 2025, total 4,728 had six-month HIV VL results available. After excluding 14 individuals who were already on ART before diagnosis, 142 individuals with baseline HIV VL  $< 50$  copies/mL, and 37 individuals  $< 18$  years, a total of 4,535 patients met the inclusion criteria and were ultimately included in the study (Figure 1).

Among the 4,535 included PLWH, 81.9% were male and nearly half were aged  $\geq 50$  years (45.3%). Sexual transmission accounted for nearly all cases (99.3%). The mean baseline plasma HIV VL was  $4.57 \pm 0.94$  log<sub>10</sub> copies/mL. The CD4 count  $< 200$  cells/ $\mu$ L was observed in 44.4% of participants. By core drug class, 63.7% were on non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimens, 1.7% on

protease inhibitor (PI)-based regimens, and 34.6% on integrase strand transfer inhibitor (INSTI)-based regimens (Table 1).

### **Six-Month Virological Failure Rate**

Six-month VF rates stratified by baseline demographic and clinical subgroups were presented in Table 1. The overall six-month VF rate during 2022-2025 was 6.8%.

In univariate analyses, male sex; older age (30-49 and  $\geq 50$  years vs 18-29 years); lower education (high school or below); illicit drug use; NNRTI-based initial ART regimen; higher baseline HIV-RNA; baseline CD4 <200 cells/ $\mu$ L; WHO stage IV; and prior prophylaxis for opportunistic infections were each significantly associated with 6-month VF (all  $p < 0.05$ ) (Table 2).

### **Risk Factors Associated with Six-Month Virological Failure**

In multivariable logistic regression, female (vs. male, aOR=0.65, 95% CI: 0.46-0.93,  $p=0.017$ ), INSTI-based ART (vs. NNRTI-based regimens, aOR=0.35, 95% CI: 0.26-0.48,  $p < 0.001$ ), CD4 count 200-349 cells/ $\mu$ L (vs. 0-199 cells/ $\mu$ L, aOR=0.57, 95% CI: 0.41-0.79,  $p < 0.001$ ) and CD4 count 350-499 cells/ $\mu$ L (vs. 0-199 cells/ $\mu$ L, aOR=0.54, 95% CI: 0.35-0.85,  $p=0.007$ ) were associated with lower risk of VF occurrence. HIV Infection through illicit drug use (vs. sexual, aOR=9.88, 95% CI: 2.90-33.61,  $p < 0.001$ ), higher baseline HIV VL (aOR=1.83, 95% CI: 1.57-2.13,  $p < 0.001$ ) were associated with the higher risk of VF occurrence. (Table 2).

## **Discussion**

In this real-world, retrospective cohort study of treatment-naïve PLWH in Hubei Province, we observed overall six-month VF rate for 2022–2025. We also identified several independent risk factors significantly associated with early VF, including male sex, infection via illicit drug use, NNRTI-based initial regimens, poorer baseline immune status, and higher baseline HIV VL. These findings provide recent and valuable information on short-term ART outcomes in China and may inform targeted early management and monitoring strategies.

In our cohort, six-month VF rate between 2022 and 2025 was 6.8%. Direct cross-study comparisons are constrained by systematic differences in study design, most notably follow-up duration, the timing of virological endpoints, and the thresholds used to define VF. For example, an African cohort reported a six-month VF of approximately 9% between 2013–2017<sup>[10]</sup>, while a large retrospective study in Thailand including patients who initiated ART between 2014 and 2018 reported a VF rate of about 2.4%<sup>[11]</sup>. Other cohorts with longer follow-up have reported different estimates. A retrospective cohort study conducted in Israel from 2010 to 2018 with a median follow-up of two years observed an overall VF rate of approximately 5.8%<sup>[12]</sup>. In China, a retrospective cohort of treatment-naïve patients from 2016–2022 reported a one-year VF rate of 1.6%<sup>[13]</sup>, and a systematic review and meta-analysis estimated an overall ART treatment failure rate of roughly 10.5%<sup>[9]</sup>. Importantly, earlier studies and some WHO-based

definitions commonly used  $\geq 1000$  copies/mL to define VF, whereas more recent studies and international guidelines increasingly adopt  $\geq 200$  copies/mL as a more clinically sensitive threshold<sup>[3–5, 14]</sup>. Given these systematic differences in follow-up time and VF definitions, VF rates reported from different settings are not directly comparable. Nevertheless, when interpreted in the context of each study's design and definitions, these short-term virological outcomes remain informative for assessing progress toward the UNAIDS 95-95-95 goal of achieving viral suppression in 95% of people receiving ART<sup>[15]</sup> and for guiding targeted monitoring and intervention strategies.

In this study, male was an independent risk factor for VF at 6 months. While relatively few studies have specifically assessed virological response at the six-month timepoint in treatment-naïve patients, most studies with longer follow-up report findings consistent with ours. A study in West Africa reported a significantly higher risk of VF in men compared with women<sup>[16]</sup>. A rural cohort from Cameroon observed higher rates of VF among men, accompanied by poorer immune recovery and more rapid progression to death and clinical disease<sup>[17]</sup>. A large retrospective study in China showed that women were more likely to achieve virological suppression at 12 and 48 months and had lower mortality than men<sup>[18]</sup>. By contrast, the ICONA cohort in Italy, after excluding women who discontinued therapy for pregnancy, did not observe a significant difference in treatment failure between sexes<sup>[19]</sup>, and an earlier European study similarly found no significant sex effect on VF<sup>[20]</sup>. Overall, most studies indicate higher rates of VF among treatment-naïve men, which may result from an interaction of biological factors, behavioral factors, and socioeconomic factors<sup>[21, 22]</sup>. In China, male account for a growing proportion of PLWH and of new HIV infections<sup>[23]</sup>. Therefore, clinical practice should pay particular attention to early treatment outcomes in male patients and reinforce targeted early interventions, including intensified adherence counseling and follow-up, proactive monitoring and management of adverse events, and regimen optimization when clinically indicated.

Consistent with prior research, our study shows that higher baseline HIV VL and low CD4 count are significantly associated with VF at 6 months. High baseline VL indicates more active viral replication and greater viral genetic diversity, which increases the risk of resistance mutations and can reduce ART effectiveness. Similarly, low baseline CD4 count not only signals immune impairment with higher risks of opportunistic infections and complications, but may also lead to incomplete immune recovery during ART, which undermines maintenance of virologic suppression and raises the likelihood of resistance related treatment failure. Furthermore, evidence from large cohorts supports these associations. The European RESPOND cohort reported that baseline VL greater than 100,000 copies/mL is associated with lower virologic suppression rates and higher risk of VF, and that low baseline CD4 count, particularly  $\leq 200$  or  $< 50$  cells/ $\mu$ L, are important predictors of failure<sup>[24]</sup>. The PopART study in South Africa showed that patients with baseline CD4 count  $\geq 500$  cells/ $\mu$ L achieved superior virologic suppression and the lowest incidence of failure<sup>[25]</sup>, while a UK cohort associated low baseline CD4 count with resistance-related failure<sup>[26]</sup>. In China, late diagnosis remains common, and many patients present with AIDS<sup>[27]</sup>; consequently, these data support more refined risk stratification of treatment-naïve HIV patients

and the prioritization of patients with high VL or poor immune status for regimens with higher genetic barriers, shorter monitoring intervals, and intensified adherence support to reduce early VF and the emergence of resistance.

In our study, infection via drug using was significantly associated with VF at six months. Many studies have shown that PLWH who use drugs, especially those who inject, often experience higher rates of VF after ART. A cohort study in China found that people who inject drugs receiving methadone maintenance treatment or who had ceased drug use had markedly higher rates of viral suppression than those remaining actively dependent<sup>[28]</sup>. Research from Greece further emphasized that active drug use is significantly negatively associated with treatment completion and sustained virologic response, and recommended interventions such as opioid substitution therapy to improve outcomes<sup>[29]</sup>. In light of these findings, we recommend strengthening drug cessation support and facilitating access to substitution therapies for PLWH who use drugs to improve outcomes of ART.

When considering virological outcomes, the choice of initial regimen is particularly important. Our cohort demonstrated a significantly higher six-month VF rate for NNRTI-based versus INSTI-based regimens (8.2% vs. 4.1%,  $p < 0.001$ ); initiation of INSTIs in treatment-naïve PLWH was associated with a lower risk of treatment failure. To clarify, the NNRTI group in this study consisted predominantly of efavirenz (EFV)-based regimens (86.91%). Therefore, the observed difference largely reflects the performance of EFV-based NNRTI therapy. INSTIs are generally characterized by a higher barrier to resistance, stronger antiviral potency, and better tolerability, which facilitate more rapid initial viral suppression and more durable virological control<sup>[30]</sup>. By contrast, the older generation of NNRTIs, represented by EFV, have a lower resistance barrier and are associated with more central nervous system adverse effects (e.g., dizziness, sleep disturbance, and mood disorders), which can lead to treatment interruptions or reduced adherence and thereby increase the risk of treatment failure or resistance<sup>[31]</sup>. Socioeconomic and health-system factors may further influence regimen choice: because of financial constraints or concerns that using drugs reimbursed by medical insurance may disclose their HIV status during reimbursement procedures, some patients prefer NNRTI regimens included in the free drug list. Delays in including newer agents in the medical insurance drug list and stricter reimbursement requirements can also limit INSTIs availability for low-income or community-level patients<sup>[32]</sup>, thereby increasing population-level exposure to NNRTI regimens with lower resistance barriers and potentially partly explaining the higher VF rate observed. Compared with previous studies, the evidence is not entirely consistent. Many studies have reported that INSTIs are associated with lower VF risk or more durable virological suppression than NNRTIs in the short or long term; a study in Liberia found a significantly lower VF incidence with dolutegravir (DTG) than with NNRTIs (5.3% vs. 14%)<sup>[33]</sup>. However, a large UK cohort study reported a higher VF risk among PLWH initiating INSTIs after adjustment for confounders (aHR = 1.52, 95% CI: 1.19–1.95,  $p = 0.0009$ ), which the authors attributed in part to prescribing selection bias<sup>[34]</sup>. Overall, differences in patient populations, prescribing practices, and resource settings may explain the inconsistent treatment effects observed. Further studies, ideally prospective and with

improved adjustment for confounders, are needed to confirm our findings and to evaluate the roles of drug efficacy, adherence, and access to reimbursed treatments.

Although the six-month VF rate and its associated factors are reported, this study has several limitations. First, adherence to ART is critical for treatment success; inadequate adherence can lead to VF, emergence of resistance, and disease progression. Adherence information typically comes from clinical records or patient-reported outcomes (PROs), but no such records were available in this CDC-based dataset. Therefore, the effect of adherence on VF could not be assessed in this study. Second, the study lacked genotypic resistance testing results at baseline and at treatment failure, so it was not possible to identify whether the observed VF were driven by resistance mutations. The absence of resistance testing not only limits understanding of the causes of failure but also prevents direct comparison of failure mechanisms across different drug classes. When investigating treatment effectiveness, future studies should include systematic adherence assessment and routinely collect genotypic resistance data to better clarify the reasons for treatment failure and to guide individualized therapy adjustments.

## Conclusions

In this real-world retrospective study of treatment-naïve patients in Hubei, the overall six-month VF rate between 2022 and 2025 was 6.8%. There was no significant difference in six-month VF rates between years. Risk factors significantly associated with six-month VF were male sex, high baseline VL, low baseline CD4 count, infection via illicit drug use, and initiation on NNRTI-based regimens. These findings support implementing more refined risk stratification at baseline, optimizing first-line regimen selection, and improving follow-up strategies to enhance early treatment outcomes and thereby improve long-term clinical prognosis.

## Abbreviations

ART  
Antiretroviral Therapy  
PLWH  
People Living with HIV  
HIV  
Human Immunodeficiency Virus  
AIDS  
Acquired Immune Deficiency Syndrome  
CI  
Confidence Interval  
VF  
Virological Failure  
VL

Virological Load  
NNRTI  
Non-Nucleoside Reverse Transcriptase Inhibitor  
PI  
Protease Inhibitor  
INSTI  
Integrase Strand Transfer Inhibitor  
EFV  
Efavirenz  
PROs  
Patient-Reported Outcomes  
IQR  
Interquartile Range  
Ors  
Odds Ratios  
CIs  
Confidence Intervals

## Declarations

### **Ethics approval and consent to participate**

Ethical approval was granted by the Medical Ethics Committee, Wuhan Jinyintan Hospital, Tongji Medical College of Huazhong University of Science and Technology. The reference number is KY-GR-2025-33. All participants included in this study provided their written informed consent prior to participation.

### **Consent for publication**

Not applicable.

## Competing interests

The authors declare no conflict of interest.

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## Author Contribution

LK and TH designed the whole experiment, participated in the data collection and analysis, and were major contributors to drafting the manuscript. ZJ, LY, CL and LL contributed to data collection. HK and ZD were responsible for the analysis and manuscript drafting. QS, and HQ modified the manuscript. All authors read and approved the submitted version.

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## Availability of data and materials

Not applicable.

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## Tables

Tables are available in the Supplementary Files section.

## Figures

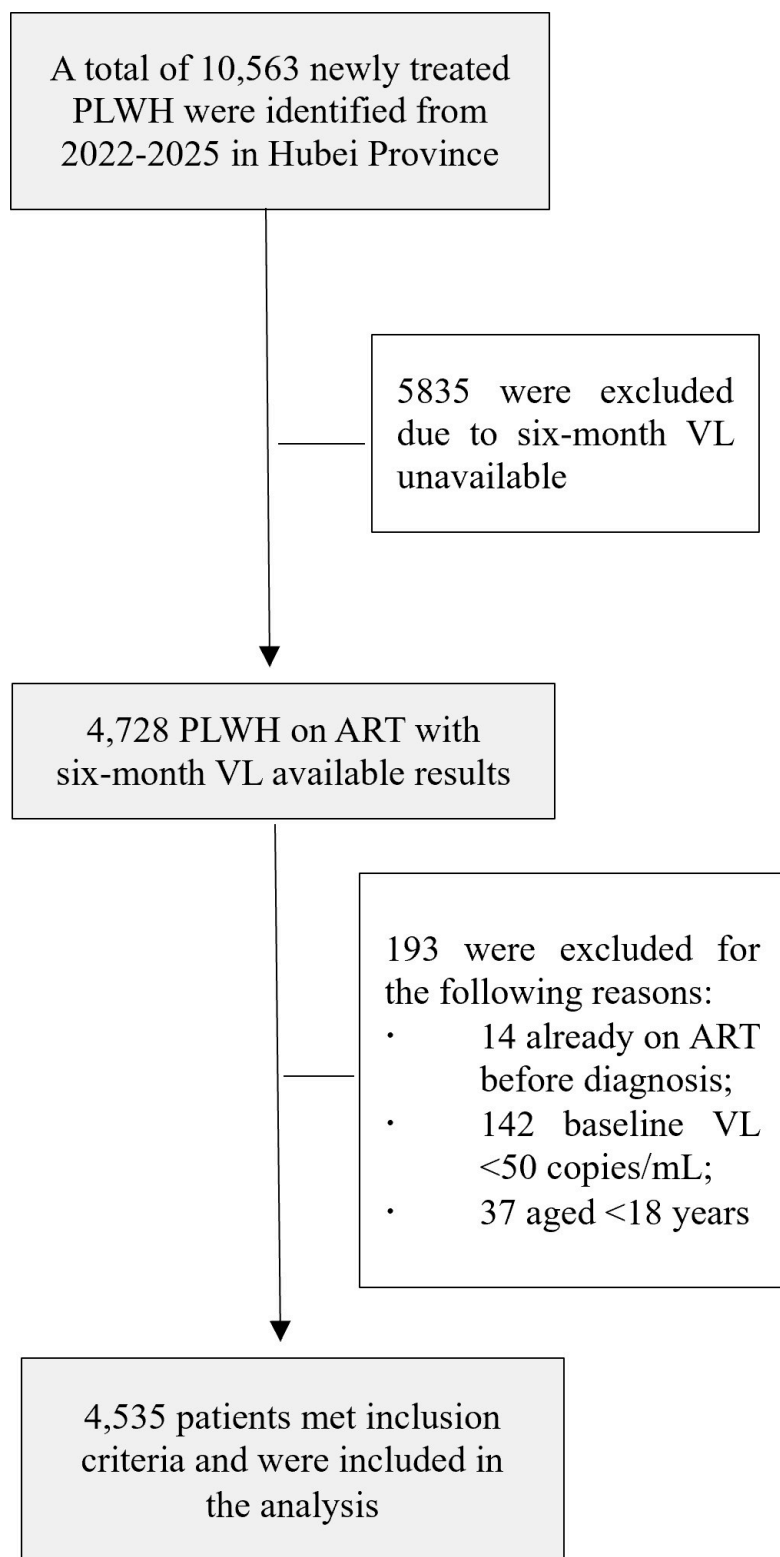


**Figure 1**

**Flow chart of study participant enrollment**

## Supplementary Files

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