

## Research Article

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## Characterization of Virologic-Immunologic Failure and Discordance among Newly Diagnosed HIV-Infected Adults in the Upper Southern Region of Thailand

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### ABSTRACT

Virologic-immunologic failure and discordance are critical predictors of clinical outcomes in HIV-infected individuals. CD4+ T lymphocyte count (CD4) and HIV viral load are routinely used to monitor and assess responses to antiretroviral therapy (ART). This retrospective descriptive study aimed to examine the prevalence of virologic-immunologic failure and discordance, as well as to investigate associated factors, including sex, age, baseline CD4 count before ART initiation, clinical symptoms, ARV regimen modifications during treatment, occupation, marital status, pregnancy status, history of previous infections, opportunistic infections during ART, and viral load >1,000 copies/mL at least six months post-ART initiation among newly diagnosed HIV-infected adults in the upper southern region of Thailand. Participants received first-line ART for at least six months between 2021 and 2023. Data were analyzed using percentages, means, medians, chi-square tests, and odds ratios.

Of the 492 participants, 68.3% were male and 31.7% were female, with a mean age of 37.3 years. The median baseline CD4 count before ART initiation was 250 cells/ $\mu$ L. Most participants received TDF+FTC+EFV (44.7%) or TLD (42.3%) as initial ART. Approximately 31.5% of participants were employed in general occupations, 54.9% were single, and 70.7% were asymptomatic at diagnosis. Among these, 23 experienced virologic failure, 41 had immunologic failure, 2 had both virologic and immunologic failure, 32 exhibited virologic discordance, and 21 showed immunologic discordance. Factors significantly associated with virologic failure included age <30 years (OR 3.5), ARV regimen modifications during treatment (OR 0.4), pregnancy status (OR 21.3), and viral load >1,000 copies/mL at least six months post-ART initiation (OR 29.9). Baseline CD4 count <200 cells/ $\mu$ L before ART initiation was significantly associated with immunologic failure.

The study population represented 2.2% of all newly diagnosed HIV-infected adults in Thailand, suggesting effective HIV management measures. Although the median baseline CD4 count was higher than in previous studies from eastern Thailand, 43.9% had a CD4 count <200 cells/ $\mu$ L, indicating delayed diagnosis and increased risk of opportunistic infections. The low rates of virologic-immunologic failure and discordance may reflect the high efficacy of current ART regimens. Both viral load and CD4 count remain essential for accurate diagnosis and monitoring. Notably, pregnant participants and those with a viral load >1,000 copies/mL after ART initiation had a markedly higher risk of virologic failure.

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### Introduction

Thailand has made continuous progress in the provision of care and treatment for people living with HIV (PLHIV), particularly through the use of antiretroviral therapy (ART). A key national objective is to end the AIDS epidemic by 2030, which has driven the evolution of HIV service delivery models. In 2014, Thailand introduced a major policy change: the initiation of ART regardless of CD4 lymphocyte count level [1]. This approach enables newly diagnosed individuals to access ART early, while their immune systems are still intact, thereby reducing the risk of disease progression. However, the successful implementation of early ART requires patient readiness and adherence to long-

term therapy. The primary goals of ART are to achieve sustained viral suppression (HIV viral load <50 copies/mL) and maintain this suppression for the longest duration possible, while restoring CD4 counts to normal levels, thereby preventing AIDS-related illnesses and reducing the burden of non-AIDS comorbidities [2].

Data from Thailand's Division of AIDS and STIs in 2024 showed persistent treatment coverage gaps. Among an estimated 565,598 PLHIV, 495,813 (87.7%) were currently receiving ART, with approximately 8,124 new cases of HIV infection being reported. According to the 95-95-95 strategy targets in 2024, 95.5% of the estimated 565,598 PLHIV were diagnosed and aware of their status; 92% of diagnosed individuals were on ART; and 89.6% of people on ART had viral suppression, highlighting the critical impact of treatment access [3].

While ART is generally associated with decreasing viral load and increasing CD4 count, clinical experience has identified a subset of patients with virologic-immunologic discordance: those who demonstrate a good immunologic response despite detectable viral load, or conversely, those who suppress viral load to an undetectable level but still experience poor immunologic recovery [4]. Therefore, understanding patterns of virologic failure, immunologic failure, and virologic-immunologic discordance is essential for predicting clinical outcomes and optimizing care strategies. The early and accurate diagnosis of virologic failure represents the most critical aspect of treatment monitoring, as it must be identified before patients progress to immunologic failure and subsequent clinical failure. This timely recognition is essential for preventing the accumulation of drug-resistant mutations that could compromise the effectiveness of current and future therapeutic options, including newer drugs within the same class [5]. Consequently, determining immuno-virologic discordant responses and associated risk factors in PLHIV on Highly Active Antiretroviral Therapy (HAART) is crucial for policymakers and healthcare providers in their efforts to achieve the goal of ending AIDS - related epidemics by 2030. Moreover, understanding virologic-immunologic failure and virologic-immunologic discordance patterns is vital for predicting clinical outcomes, informing regimen changes, and optimizing management strategies for PLHIV on HAART. However, data in Thailand remain scarce. Therefore, this study aims to assess the prevalence of virologic-immunologic failure and virologic-immunologic discordance, along with an examination of factors affecting virologic and immunologic failure among new HIV-infected adults in the upper southern region of Thailand.

## Methods

This was a retrospective descriptive study conducted among new HIV-infected patients who initiated antiretroviral therapy. Specimens were collected from the hospitals across seven provinces in the upper southern region of Thailand, including Chumphon, Ranong, Surat Thani, Phang Nga, Phuket, Krabi, and Nakhon Si Thammarat, and were tested at the Public Health Laboratory, The Office of Disease Prevention and Control Region 11, Nakhon Si Thammarat province. The study utilized data from CD4 count and HIV viral load test results obtained from the National AIDS Program Web Report (NAPPLUS Web Report) system [6]. Initially, 538 newly diagnosed HIV-infected patients were identified during the study period. The inclusion criteria for the study population were as follows: (1) new HIV-infected individuals aged 15 years and older; (2) availability of CD4 count results both before ART initiation and after at least 6 months of antiretroviral treatment; and (3) at least one HIV viral load measurement during the follow-up period. After applying these criteria, 492 patients were included in the final analysis.

## Definitions of Terms

- Virologic failure is defined as the failure to achieve or sustain suppression of viral replication. This is characterized by an HIV viral load equal to or greater than 200 copies/mL after at least six months of highly active antiretroviral therapy (HAART) initiation.
- Immunologic failure is defined as a CD4 count equal to or less than the pre-HAART initiation level or below 100 cells/ $\mu$ L on consecutive measurements.
- Virologic discordant is defined as suppressed viral load with inadequate immunologic recovery, characterized by HIV viral load < 50 copies/mL concurrent with CD4 count equal to or less than the pre-HAART initiation level or below 100 cells/

$\mu$ L on consecutive measurements.

- Immunologic discordant is defined as adequate immunologic recovery with unsuppressed viral load, characterized by CD4 count higher than the pre-HAART initiation level and above 100 cells/ $\mu$ L on consecutive measurements, concurrent with HIV viral load  $\geq$  200 copies/mL.

## Data Analysis

Laboratory data, including CD4 count (BD FACS ViaTM; Becton Dickinson, USA) and HIV-1 viral load (cobas® 6800 system; Roche Diagnostics, USA) in patients initiating first-line antiretroviral therapy, were analyzed using descriptive statistics including frequency percentage, mean, and median to assess virologic failure, immunologic failure, and discordant response. Pearson chi-square test and odds ratio were used to examine associations between potential risk factors and virological or immunological failure. Statistical significance was set at p-value < 0.05.

In this study examining factors associated with virologic and immunologic failure, eleven variables were evaluated, including sex, age, baseline CD4 count before ART initiation, clinical symptoms, ARV regimen modifications during treatment, occupation, marital status, pregnancy status, history of previous infections, opportunistic infections during ART, and viral load > 1,000 copies/mL at least six months post-ART initiation.

## Results

Between 2021 and 2023, out of 538 newly diagnosed HIV-infected participants, 492 cases were included in the study for outcome analysis. Demographic characteristics showed that the majority of participants were male, with 336 participants (68.3%) compared to 156 females (31.7%). The mean age was 37.3 years, with an interquartile range of 27–46 years. Age distribution analysis showed that participants aged 31–50 years constituted the largest proportion (47.2%), followed by those aged 15 to 30 years (35.0%), and those older than 50 (17.9). The median baseline CD4 count before ART initiation was 250 cells/ $\mu$ L (IQR: 75–469). Distribution analysis showed that participants with CD4 counts of 50–200 cells/ $\mu$ L comprised the largest proportion (23.6%), followed by those with CD4 count > 500 cells/ $\mu$ L (21.7%), those with CD4 count of 201–350 cells/ $\mu$ L (20.7%), those with CD4 count < 50 cells/ $\mu$ L (20.3%), and those with CD4 count of 351–500 cells/ $\mu$ L (13.6%). Regarding the first-line ART regimen, the most frequently used treatment was tenofovir disoproxil fumarate (TDF) with emtricitabine (FTC) and efavirenz (EFV), accounting for 44.7% of participants, followed by the three-drug combination of tenofovir disoproxil fumarate, lamivudine (3TC), and dolutegravir (DTG), also known as TLD, with 42.3%. Regarding occupational distribution, general employees comprised the majority of participants at 31.5%. Additionally, students and prisoners collectively represented approximately 8% of the study population. The results also demonstrated that 55% of participants were unmarried, and 70% presented asymptotically. The study identified immunologic-virologic success in 373 cases (75.8%). Virologic failure was observed in 23 cases (4.7%), while immunologic failure occurred in 41 cases (8.3%). Cases of virologic discordance and immunologic discordance were identified in 32 (6.5%) and 21 (4.3%) participants, respectively. Notably, concordant non-responders with combined virologic and immunologic failure were found in only 2 cases (0.4%), as summarized in Table 1.

**Table 1: Demographic and Clinical Characteristics of People Living with HIV Receiving Antiretroviral Therapy during 2021–2023 (n = 492)**

| Data                                                                                                   | Number (N) | Percentage (%) |
|--------------------------------------------------------------------------------------------------------|------------|----------------|
| Sex                                                                                                    |            |                |
| Male                                                                                                   | 336        | 68.3           |
| Female                                                                                                 | 156        | 31.7           |
| Age (mean 37.3 years, IQR 27-46)                                                                       |            |                |
| 15-30                                                                                                  | 172        | 35.0           |
| 31-50                                                                                                  | 232        | 47.2           |
| >50                                                                                                    | 88         | 17.9           |
| <b>Baseline CD4 Count Before ART Initiation (cells/μL) Median (inter quartile range): 250 (75-469)</b> |            |                |
| <50                                                                                                    | 100        | 20.3           |
| 50-200                                                                                                 | 116        | 23.6           |
| 201-350                                                                                                | 102        | 20.7           |
| 351-500                                                                                                | 67         | 13.6           |
| >500                                                                                                   | 107        | 21.7           |
| <b>First-line ART regimen</b>                                                                          |            |                |
| TDF + EFV + 3TC                                                                                        | 27         | 5.5            |
| TDF + FTC + EFV                                                                                        | 220        | 44.7           |
| TLD                                                                                                    | 208        | 42.3           |
| 3TC + TDF + DTG                                                                                        | 6          | 1.2            |
| GPO-VIR Z<br>(AZT 250 + 3TC 150 + NVP 200)                                                             | 5          | 1.0            |
| Others                                                                                                 | 26         | 5.3            |
| <b>Occupation</b>                                                                                      |            |                |
| General employees                                                                                      | 155        | 31.5           |
| Agriculturalists                                                                                       | 63         | 12.8           |
| Unemployed                                                                                             | 55         | 11.2           |
| Company employees                                                                                      | 30         | 6.1            |
| Students                                                                                               | 20         | 4.1            |
| Trades                                                                                                 | 18         | 3.7            |
| Prisoners                                                                                              | 18         | 3.7            |
| Others                                                                                                 | 133        | 27.0           |
| <b>Marital Status</b>                                                                                  |            |                |
| Single                                                                                                 | 270        | 54.9           |
| Married                                                                                                | 165        | 33.5           |
| Divorced                                                                                               | 57         | 11.6           |
| <b>Clinical Stage of HIV Infection</b>                                                                 |            |                |
| Asymptomatic                                                                                           | 348        | 70.7           |
| Symptomatic                                                                                            | 91         | 18.5           |
| AIDS                                                                                                   | 53         | 10.8           |
| <b>Immunologic-Virologic Success</b>                                                                   | 301        | 61.2           |
| <b>Virologic Failure</b>                                                                               | 23         | 4.7            |
| <b>Virologic Discordance</b>                                                                           | 32         | 6.5            |
| <b>Immunologic Failure</b>                                                                             | 41         | 8.3            |
| <b>Immunologic Discordance</b>                                                                         | 21         | 4.3            |
| <b>Concordant non-responders</b>                                                                       | 2          | 0.4            |

\* TDF, Tenofovir Disoproxil Fumarate; EFV, Efavirenz; 3TC, Lamivudine; FTC, Emtricitabine; TLD, Tenofovir Disoproxil Fumarate + Lamivudine + Dolutegravir (DTG); GPO–VIRZ, Nevirapine (NVP) + Lamivudine + Zidovudine (AZT).

In this study examining factors associated with virologic and immunologic failure, eleven variables were evaluated (Tables 2 and 3): sex, age, baseline CD4 count before ART initiation, clinical symptoms, ARV regimen modifications during treatment, occupation, marital status, pregnancy status, history of previous infections, opportunistic infections during ART, and viral load >1,000 copies/mL at least six months post-ART initiation. Four variables were found to be statistically associated with virologic failure ( $p$ -value <0.05): age, viral load >1,000 copies/mL at least six months post-ART initiation, ARV regimen modifications during treatment, and pregnancy status. Notably, pregnant participants and those with a viral load >1,000 copies/mL after ART initiation had a markedly higher risk of virologic failure, with odds ratios of 21.3 and 29.9, respectively. For immunologic failure, only baseline CD4 count before ART initiation showed statistical significance. Participants with baseline CD4 counts <200 cells/ $\mu$ L had a five-fold increased risk of immunologic failure (OR = 5.0,  $p$ -value <0.05).

**Table 2: The Correlation Between Studied Factors and Virologic Failure**

| Data                                                                          | Total (n=492) | Virologic failure (n=23) | $p$ -value    | Odds ratio |
|-------------------------------------------------------------------------------|---------------|--------------------------|---------------|------------|
| <b>Sex</b>                                                                    |               |                          |               |            |
| Male                                                                          | 336           | 13                       | 0.214         | 0.604      |
| Female                                                                        | 156           | 10                       |               |            |
| <b>Age</b>                                                                    |               |                          |               |            |
| <30                                                                           | 172           | 15                       | <b>0.002*</b> | 3.488      |
| $\geq$ 30                                                                     | 320           | 8                        |               |            |
| <b>Baseline CD4 count before ART initiation</b>                               |               |                          |               |            |
| <200                                                                          | 276           | 11                       | 0.413         | 0.717      |
| $\geq$ 200                                                                    | 216           | 12                       |               |            |
| <b>Clinical Symptoms</b>                                                      |               |                          |               |            |
| Symptomatic                                                                   | 144           | 6                        | 0.731         | 0.853      |
| Asymptomatic                                                                  | 348           | 17                       |               |            |
| <b>ARV Regimen Modifications During Treatment</b>                             |               |                          |               |            |
| No ARV regimen modifications                                                  | 292           | 9                        | <b>0.043*</b> | 0.440      |
| ARV regimen modifications                                                     | 200           | 14                       |               |            |
| <b>Occupation</b>                                                             |               |                          |               |            |
| Yes                                                                           | 437           | 23                       | 0.081         | N/A        |
| No                                                                            | 55            | 0                        |               |            |
| <b>Marital Status</b>                                                         |               |                          |               |            |
| Yes                                                                           | 222           | 11                       | 0.790         | 1.115      |
| No                                                                            | 270           | 12                       |               |            |
| <b>Pregnancy Status</b>                                                       |               |                          |               |            |
| Yes                                                                           | 24            | 12                       | <b>0.000*</b> | 21.273     |
| No                                                                            | 468           | 11                       |               |            |
| <b>History of Previous Infections</b>                                         |               |                          |               |            |
| Yes                                                                           | 22            | 0                        | 0.288         | 0.000      |
| No                                                                            | 470           | 23                       |               |            |
| <b>Opportunistic Infections During ART</b>                                    |               |                          |               |            |
| Yes                                                                           | 38            | 1                        | 0.535         | 0.543      |
| No                                                                            | 454           | 22                       |               |            |
| <b>Viral Load &gt;1,000 Copies/mL at Least Six Months Post-ART Initiation</b> |               |                          |               |            |
| Yes                                                                           | 35            | 16                       | <b>0.000*</b> | 29.845     |
| No                                                                            | 457           | 7                        |               |            |

\* $p$ -value <0.05

**Table 3: The Correlation Between Studied Factors and Immunologic Failure**

| Data                                                                          | Total (n=492) | Immunologic failure (n=41) | p-value | Odds ratio |
|-------------------------------------------------------------------------------|---------------|----------------------------|---------|------------|
| <b>Sex</b>                                                                    |               |                            |         |            |
| Male                                                                          | 336           | 30                         | 0.483   | 1.266      |
| Female                                                                        | 156           | 11                         |         |            |
| <b>Age</b>                                                                    |               |                            |         |            |
| <30                                                                           | 172           | 16                         | 0.569   | 1.191      |
| ≥30                                                                           | 320           | 25                         |         |            |
| <b>Baseline CD4 Count before ART Initiation</b>                               |               |                            |         |            |
| <200                                                                          | 276           | 36                         | 0.000*  | 5.635      |
| ≥200                                                                          | 216           | 5                          |         |            |
| <b>Clinical symptoms</b>                                                      |               |                            |         |            |
| Symptomatic                                                                   | 144           | 10                         | 0.473   | 0.780      |
| Asymptomatic                                                                  | 348           | 31                         |         |            |
| <b>ARV Regimen Modifications During Treatment</b>                             |               |                            |         |            |
| No ARV regimen modifications                                                  | 292           | 26                         | 0.580   | 1.187      |
| ARV regimen modifications                                                     | 200           | 15                         |         |            |
| <b>Occupation</b>                                                             |               |                            |         |            |
| Yes                                                                           | 437           | 40                         | 0.064   | 5.034      |
| No                                                                            | 55            | 1                          |         |            |
| <b>Marital Status</b>                                                         |               |                            |         |            |
| Yes                                                                           | 222           | 15                         | 0.251   | 0.702      |
| No                                                                            | 270           | 26                         |         |            |
| <b>Pregnancy Status</b>                                                       |               |                            |         |            |
| Yes                                                                           | 24            | 1                          | 0.449   | 0.488      |
| No                                                                            | 468           | 40                         |         |            |
| <b>History of Previous Infections</b>                                         |               |                            |         |            |
| Yes                                                                           | 22            | 0                          | 0.148   | 0.000      |
| No                                                                            | 470           | 41                         |         |            |
| <b>Opportunistic Infections During ART</b>                                    |               |                            |         |            |
| Yes                                                                           | 38            | 1                          | 0.186   | 0.299      |
| No                                                                            | 454           | 40                         |         |            |
| <b>Viral Load &gt;1,000 Copies/mL at Least Six Months Post-ART Initiation</b> |               |                            |         |            |
| Yes                                                                           | 35            | 2                          | 0.561   | 0.670      |
| No                                                                            | 457           | 39                         |         |            |

\*p-value <0.05

## Discussion

This retrospective descriptive study provides important insights into the patterns of virologic failure, immunologic failure, and virologic-immunologic discordance among newly diagnosed HIV-infected adults in the upper southern region of Thailand. The findings have significant implications for HIV treatment strategies, monitoring, and public health policy, particularly in the context of Thailand's goal to end the AIDS epidemic by 2030.

The study population was predominantly male (68.3%) with a median baseline CD4 count of 250 cells/μL, consistent with regional and national HIV epidemiology. The majority of participants received TDF+FTC+EFV or TLD regimens, reflecting current first-line ART practices in Thailand known for their efficacy and tolerability [7]. Despite policy changes allowing ART initiation regardless of CD4 count, a substantial proportion (43.9%) presented with baseline CD4 counts below 200 cells/μL, indicating delayed diagnosis and linkage to care [8]. This delay increases the risk of opportunistic infections, underscoring the need for intensified HIV testing and earlier treatment initiation.

For virologic and immunologic outcomes, the overall rates of virologic failure (4.7%) and immunologic failure (8.3%) were low, as were the rates of virologic (6.5%) and immunologic discordance (4.3%). These results align with previous studies demonstrating the high effectiveness of contemporary ART regimens in achieving viral suppression and immune recovery [9]. The very low rate of concordant non-responders (0.4%) further supports the efficacy of current treatment protocols.

The finding that a viral load >1,000 copies/mL at least 6 months post-ART initiation is strongly associated with virologic failure (OR =29.9) aligns with global definitions of virologic failure, which emphasize persistent viral replication above 200 copies/mL as a key marker of treatment failure and risk for drug resistance development. This underscores the critical importance of early viral load monitoring to promptly identify and address virologic failure before clinical progression or immunologic decline occurs [10]. Pregnancy status was also significantly associated with virologic failure (OR =21.3), highlighting the need for targeted adherence support and close monitoring of pregnant women living with HIV to ensure optimal ART outcomes and prevent mother-to-child transmission. Younger age (<30 years) was another risk factor for virologic failure, possibly reflecting challenges in adherence or social determinants affecting this group.

In contrast, immunologic failure was mainly associated with a low baseline CD4 count (<200 cells/ $\mu$ L) before ART initiation (OR=5.0), indicating that delayed diagnosis and treatment initiation remain critical issues. Despite policy changes in Thailand promoting early ART regardless of CD4 count since 2014 [1], a substantial proportion of patients still present late with advanced immunosuppression, increasing their risk of opportunistic infections and poor immunologic recovery. This finding concurs with global evidence supporting early ART initiation for optimal immunologic outcomes [11].

The discordance patterns observed—virologic discordance (6.5%) and immunologic discordance (4.3%)—reflect the complex interplay between viral suppression and immune restoration. Such discordance can complicate clinical management, as patients may have suppressed viral loads but inadequate CD4 recovery or vice versa. This finding emphasizes the need for integrated monitoring of both viral load and CD4 counts to guide treatment decisions effectively.

These findings also underscore the critical importance of early HIV diagnosis and prompt ART initiation to prevent immunologic failure and reduce opportunistic infections. Routine monitoring of both viral load and CD4 count remains essential to identify discordant responses and guide individualized patient management and regimen adjustments. The elevated risk of virologic failure among younger adults and pregnant women suggests the need for targeted interventions to improve adherence, retention, and support in these populations. The association between ARV regimen modifications during treatment and virologic failure highlights the importance of careful regimen selection and management of side effects or drug interactions.

A significant limitation in the HIV/AIDS care system in Thailand is that, as of 2017, viral load testing before the initiation of antiretroviral therapy was not covered under the benefit package provided by the National Health Security Office, which may affect early detection of treatment failure and optimization of patient management [12]. Additionally, the retrospective design may be subject to incomplete data and unmeasured confounding factors.

The study was conducted in a specific region of Thailand, which may limit generalizability. Behavioral and psychosocial factors influencing adherence were not evaluated.

## Conclusion

In conclusion, this study demonstrates a low prevalence of virologic and immunologic failure and discordance among newly diagnosed HIV-infected adults in the upper southern region of Thailand, reflecting the high efficacy of current ART regimens. Early viral load monitoring, prompt management of virologic failure, and efforts to diagnose and treat HIV before severe immunosuppression are essential to optimize ART outcomes. However, late diagnosis and ART initiation remain challenges, and certain subgroups—particularly younger adults and pregnant women—require enhanced support. These findings support ongoing efforts to expand early HIV testing, ensure rapid ART initiation, and strengthen routine virologic and immunologic monitoring to optimize outcomes and progress toward ending the AIDS epidemic by 2030.

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