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A pilot model of centralized anti-HIV-1 drug resistance testing with decentralized treatment in resource-limited settings

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Abstract: Vietnam is a lower-middle-income country where HIV drug resistance (DR) testing is not widely accessible, and antiretroviral therapy (ART) options remain limited. Since 2016, HIV services have gradually transitioned from international donor support to national Social Health Insurance (SHI). Under the decentralized policy of SHI, HIV treatment has been delivered at local neighborhood hospitals, where experience in managing ART failure is still lacking. This study evaluated a pilot model of centralized DR testing combined with decentralized treatment implementation in Northern Vietnam. Seven provincial hospitals and three healthcare facilities participated. Patients' viral loads (VL) were monitored every six months over a 48-month period (October 2019–September 2023). ART failure was defined as VL ≥ 1,000 copies/mL, which triggered DR testing at the National Hospital for Tropical Diseases in Hanoi. Based on DR results, tailored ART recommendations were provided to local hospitals and healthcare settings. The effectiveness of subsequent ART following DR testing was assessed by VL suppression at 90 days or later. Among 179 patients experiencing ART failure, DR testing was successful in 170 cases. DR mutations were detected in 126 patients (74.12%), while 44 (25.88%) showed no mutation. Patients who followed the ART recommendations had a significantly higher VL suppression rate (87.72%) than those who did not (70.37%, $p = 0.026$). This association was significant in district hospitals (87.50% *vs.* 60.00%, $p = 0.032$) but not in provincial hospitals (87.93% *vs.* 76.47%, $p = 0.240$). This study highlights the potential clinical benefit of our model in resource-limited situations, particularly where ART management capacity is limited.

***Keywords*:** HIV, drug resistance, virological failure, treatment recommendation, resource-limited situation

Introduction

The global response to HIV has made remarkable progress, with antiretroviral therapy (ART) reaching 29.8 million people by December 2022, up from 7.7 million in 2010. Despite this advancement, HIV drug resistance (DR) has emerged as a significant challenge, with a steadily increasing prevalence that threatens to undermine treatment efficacy and efforts to control the epidemic (*1*). In resource-limited settings, where therapeutic options are constrained, effective strategies for monitoring and managing DR are essential to ensuring the long-term sustainability of available antiretroviral regimens.

Vietnam serves as a particularly illustrative case study of the challenges in managing HIV drug resistance amid a transition in the healthcare system. The country has made significant progress in its HIV response, with a concentrated epidemic primarily affecting key populations. A nationally representative survey conducted in 2023 reported encouraging advancements toward the Joint United Nations Programme on HIV/AIDS (UNAIDS) targets, with 94% of people living with HIV aware of their status, 78% receiving treatment, and 73% of those on treatment achieving viral suppression (*2*). However, this progress is threatened by two concurrent challenges: rising rates of DR and a rapid transition from international donor funding to domestic financing.

HIV drug resistance prevalence in Vietnam has increased from less than 5% to between 5 and 15% over the past decade (*3*). A national survey conducted in 2017-2018 revealed that the prevalence of any pre-treatment HIV drug resistance was 5.8% (95% CI: 3.4–9.5%), with

non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance at 3.4% (*4*). This rising resistance threatens the effectiveness of first-line regimens and underscores the need for robust monitoring systems to guide appropriate treatment decisions.

At the same time, Vietnam is navigating a challenging transition in HIV financing. International funding sources, including the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund, have historically financed the majority of Vietnam's HIV/AIDS response. However, this support has declined significantly since Vietnam transitioned to lower-middle-income country status (*5,6*). In response, Vietnam has successfully integrated HIV services into its Social Health Insurance (SHI) scheme, with domestic resources funding 53% of the HIV response by 2020 (*6*).

Effective monitoring of HIV drug resistance is essential, but it faces significant barriers in resource-limited settings like Vietnam. Sanger sequencing remains the gold standard for genotyping but is available only at a limited number of reference laboratories, with high capital and operational costs limiting broader implementation (*7*). Most HIV diagnostic facilities in resource-limited settings are centralized, requiring specialized infrastructure and trained personnel, with laboratories often located far from patients' homes. This geographic disconnect can result in delayed testing, lost results, and suboptimal patient management (*8,9*).

The decentralization of HIV care delivery presents both opportunities and challenges. Fewer than 30% of people diagnosed with HIV in resource-limited settings complete the full continuum of care, and globally, fewer than 50% of adults remain in care four years after initiating ART (*7*). Decentralizing HIV treatment and care reduces waiting times, brings services closer to patients' homes, and may improve retention. However, this approach creates a potential disconnect between centralized expertise and decentralized implementation, particularly for complex aspects of care such as interpreting resistance tests and making subsequent treatment decisions.

Growing evidence suggests that HIV resistance testing may be a more effective tool for improving HIV care where treatment options are limited (*10*). However, there is a lack of research on models that effectively bridge the gap between centralized technical expertise and decentralized treatment implementation. This study aimed to examine a pilot model of centralized HIV drug resistance testing paired with decentralized treatment implementation in Vietnam. This approach seeks to leverage specialized expertise in DR interpretation while empowering local healthcare providers to implement appropriate treatment changes.

Patients and Methods

Study design and settings

This observational cohort study was conducted as part of the "Science and Technology Research Partnership for Sustainable Development" (SATREPS) project, a collaboration between the Japanese and Vietnamese governments from October 2019 to September 2023. In this project, 11 healthcare facilities in Vietnam were connected to the HIV Data Network (HDN) system. These facilities included one national hospital (National Hospital for Tropical Diseases, NHTD), seven provincial hospitals (Quang Ninh General Hospital, Hospital 09, Nghe An General Hospital, Dong Da Hospital, Hung Yen Hospital of Tropical Diseases, Hai Duong Hospital of Tropical Diseases, and Center for Disease Control and Prevention (CDC) Ha Tinh), and three district-level healthcare facilities (Nam Tu Liem Clinic, Phu Tho-Thanh Son District Health Center, and Yen Bai-Yen Binh District Health Center). The sites were selected to represent different levels of the healthcare system and serve regions with high HIV prevalence.

Study population and recruitment

In this study, patients' HIV viral loads were assessed every six months over a 48-month period (October 2019 to September 2023). We enrolled 179 HIV-positive patients who met the following inclusion criteria: *i*) confirmed HIV diagnosis, *ii*) receiving care at one at one of the 10 provincial hospitals or district-level healthcare facilities, *iii*) on ART for at least 6 months prior to enrollment, *iv*) plasma viral load > 1,000 copies/ml (regarded as treatment failure) (*11,12*), and *v*) willing to participate and provide written informed consent. No restrictions were placed on ART regimens. Patients were recruited during their routine clinic visits.

Following enrollment, participants underwent HIV viral load testing at six-month intervals. For individuals with a viral load exceeding 1,000 copies/mL - indicative of virologic failure - genotypic resistance testing was initiated. Blood samples were collected at study sites and transported to the NHTD, typically within seven days. Upon receipt, samples were analyzed using the Roche Cobas 6800 system, which is *in vitro* diagnostic (IVD)-certified. Antiretroviral treatment adherence was assessed in accordance with the Ministry of Health's national guidelines, using a combination of patient interviews, medication audits, and other standardized monitoring approaches (*11*).

Treatment monitoring and recommendations

As noted above, patients who enrolled in this study (viral load ≥ 1,000 copies/mL) received DR testing. The DR results were reviewed by doctors at the AIDS Clinical Center (ACC) of the National Center for Global Health and Medicine (NCGM), Japan — now known as the Japan Institute for Health Security (JIHS). Based on these results, treatment recommendations

were sent to local physicians *via* the HDN system. The recommendations were classified into four categories: *i*) Continue current regimen, *ii*) Change regimen, *iii*) Either continue or change recommended, and *iv*) Polymerase Chain Reaction (PCR) failure/invalid data.

Subsequent treatment decisions made by local physicians were classified into four categories: *i*) Changed according to recommendations – the treatment regimen was modified in accordance with the recommendations provided by ACC/NCGM clinicians; *ii*) Changed not according to recommendations – the regimen was modified but not in line with the recommendations; *iii*) Maintained according to recommendations – the regimen was left unchanged, as recommended; and *iv*) Maintained not according to recommendations – the regimen was not changed despite a recommendation to modify it. Treatment decisions were considered in accordance with recommendations if the regimen was either modified according to recommendations *i*) or maintained as recommended *iii*). Conversely, decisions were considered not in accordance with recommendations if the regimen was modified contrary to recommendations *ii*) or remained unchanged despite a recommendation to switch *iv*).

Outcome evaluation

The primary goal was viral suppression (VL < 1,000 copies/mL) assessed at least 90 days after the recommendations. This 90-day period was chosen to ensure sufficient time for any treatment changes to take effect. For each patient, we recorded the ART regimen and viral load at the first follow-up visit and the time interval between the treatment recommendation and that visit. Patients who did not attend their follow-up visits were classified as "waiting" with documented reasons (*e.g.*, loss to follow-up, death, transfer). Treatment changes between Efavirenz (EFV) 600 and EFV 400 were not considered regimen changes. All data were entered into the HDN system with regular quality checks. Patient follow-up was conducted in alignment with their routine care schedule, which occurred every six months over a 48-month period.

Statistical analysis

Patient characteristics were summarized using descriptive statistics. Categorical variables were presented as frequencies and percentages, while continuous variables were reported as means ± standard deviations (SD) or medians with interquartile range (IQR). Comparisons between groups were conducted using the Chi-square or Fisher's exact test for categorical variables, and the Student's *t*-test for continuous variables.

Logistic regression analysis was used to determine factors associated with viral load suppression at least 90 days after the recommendations. The multivariate model included adherence to recommendations, gender, age groups, HIV infection duration, ART duration, and hospital level. Results were presented as odds ratios (OR) with 95% confidence intervals. *P*-values less than 0.05 were considered statistically significant. All analyses were performed using Stata version 22.0.

Ethical considerations

The study was approved by the Human Research Ethics Committee of the National Center for Global Health and Medicine (Reference: NCGM-G-003124-03), the Biomedical Research Ethics Committee of the National Hospital for Tropical Diseases (Reference: 17/HDDD-NDTU) and the Biomedical Research Ethics Committee of the Hanoi Medical University (Reference: 677/GCN-HĐĐĐNCYSH-ĐHYHN). All participants provided written informed consent. Patient data were anonymized for analysis and confidentiality was maintained throughout the study. This study was conducted in accordance with the principles of the Declaration of Helsinki.

Results

Among the 179 enrolled patients, 9 had PCR failures and could not proceed with DR testing. Of the remaining 170 patients with successful PCR, 29 cases were excluded due to a lack of 90-day follow-up (18 were waiting, 6 were lost to follow-up or transferred, and 5 had died). Ultimately, 141 patients were evaluated for treatment outcomes. These evaluable cases were analyzed based on whether they followed the treatment recommendations. Among them, 114 followed the recommendations and 27 did not (Figure 1).

Patient demographics and group-specific characteristics are presented in Table 1. The mean age was 38.80 years with a predominance of males (64.25%). The mean duration of HIV infection after diagnosis and of antiretroviral (ARV) treatment was 7.42 and 6.88 years, respectively.

Patterns of DR among study participants are shown in Figure 2. Among 170 patients with successful PCR test results, nearly half had dual-class resistance and a quarter had no resistance. These findings revealed that dual-class resistance, particularly Nucleos(t)ide Analogue Reverse Transcriptase Inhibitor (NRTI) and Non-nucleoside Analogue Reverse Transcriptase Inhibitor (NNRTI), was predominant in this patient population, while protease inhibitor (PI) resistance remained relatively uncommon, and no integrase strand transfer inhibitor (INSTI) resistance has been found to date.

ART regimens following the recommendations are listed in Table 2. The recommendations were adopted in 114 cases, while 27 were not. Based on DR results, continuation of the current regimen was advised in 63 cases (44.68%).

As noted in Figure 1, following the recommendations was significantly associated with viral load suppression (followed *vs.* not followed; 87.72% *vs.* 70.37%, p = 0.026). When the outcomes were further analyzed by facility level (Table 3), this association was statistically significant in district hospitals (followed *vs.* not followed; 87.50% *vs.* 60.00%, p = 0.032), but not in provincial hospitals (followed *vs.* not followed; 87.93% *vs.* 76.47%, p = 0.240), despite similar trends. These findings suggest that adherence to centralized DR testing recommendations has a particularly strong impact at the district level, where treatment expertise may be more limited, supporting the value of centralized DR testing with decentralized treatment implementation in resource-limited settings.

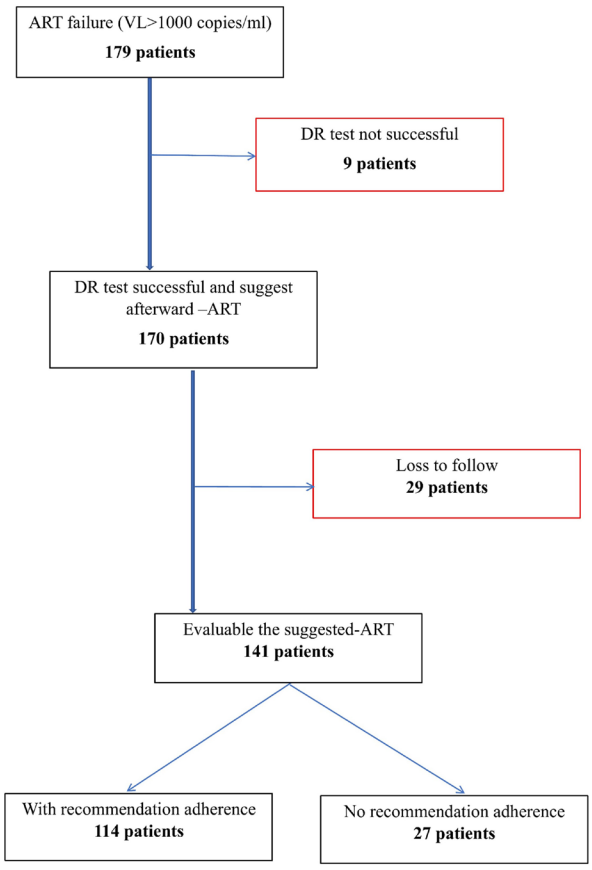

Figure 1. Flow of patients and outcomes.

In both univariate and multivariate analyses, following the recommendations was the only factor significantly associated with viral load suppression (Table 4). Patients who followed the recommendations had approximately three times higher odds of achieving viral suppression in univariate analysis (OR = 3.01, 95% CI: 1.11–8.16, p = 0.031), and this association remained strong after adjusting for other factors (adjusted OR = 3.34, 95% CI: 1.13–9.86, p = 0.029). Other factors showed no significant associations with viral suppression outcomes.

Discussion

This study documented the success of the pilot model combining centralized HIV-1 drug resistance testing with decentralized treatment in Northern Vietnam. The findings support the broader implementation of this model under the national SHI scheme across the country. Patients who followed the recommendations based on DR testing had significantly higher rates of viral suppression. Furthermore, the effectiveness of this

Table 1. Demographics of patients in this study (n = 179)

Demographics	n (%) or mean ± SD			
	Total	Recommendations followed	Recommendations not followed	Loss to follow
Age (years)	38.80 ± 11.99	38.39 ± 11.46	38.14 ± 11.78	40.37 ± 13.75
Age groups				
< 25 years	24 (13.41)	15 (13.16)	5 (18.52)	4 (10.53)
25–34 years	30 (16.76)	19 (16.67)	4 (14.81)	7 (18.42)
35–44 years	77 (43.02)	51 (44.74)	11 (40.74)	15 (39.47)
45–54 years	34 (18.99)	23 (20.18)	5 (18.52)	6 (15.79)
≥ 55 years	14 (7.82)	6 (5.26)	2 (7.41)	6 (15.79)
Gender				
Male	115 (64.25)	78 (68.42)	15 (55.56)	22 (57.89)
Female	64 (35.75)	36 (31.58)	12 (44.44)	16 (42.11)
Duration after HIV diagnosis (years)	7.42 ± 5.00	7.21 ± 4.78	7.19 ± 4.98	8.22 ± 5.72
Duration of ART (years)	6.88 ± 4.71	6.75 ±4.52	6.66 ± 4.66	7.41 ± 5.33
Route of transmission				
Sexual transmission	81 (45.25)	44 (38.60)	15 (55.56)	22 (57.89)
Injection drug use	54 (30.17)	38 (33.33)	7 (25.93)	9 (23.68)
Mother-to-child	12 (6.70)	8 (7.02)	2 (7.41)	2 (5.26)
Blood transfusion	1 (0.56)	0	0	1 (2.63)
Others/Unknown	31 (17.32)	24 (21.05)	3 (11.11)	4 (10.53)
Healthcare facilities				
7 provincial level hospitals	94 (52.51)	58 (50.88)	17 (62.96)	19 (50.0)
3 district level hospitals	85 (47.49)	56 (49.12)	10 (37.04)	19 (50.0)

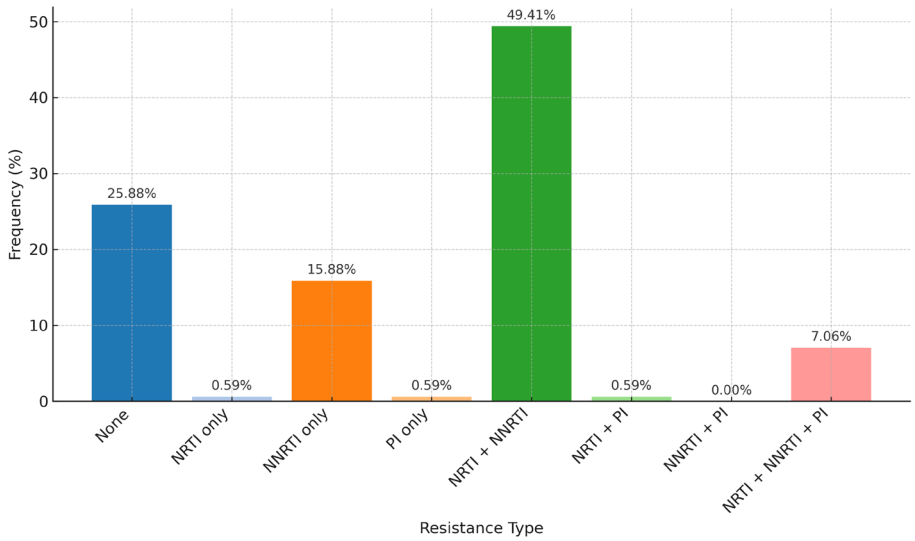

Figure 2. HIV drug resistance patterns.

Table 2. ART regimen following recommendations based on DR test results (*n* = 141)

ART after recommendations	*n*	%
Recommendations followed	114	80.85
Continued the same regimen	63	44.68
Changed key drug	51	36.17
EFV → LPV/r	28	19.86
TDF/3TC/EFV→TDF/3TC/LPV/r	12	8.51
TDF/3TC/EFV→AZT/3TC/LPV/r	14	9.93
AZT/3TC/EFV→TDF/3TC/LPV/r	2	1.42
NVP→ LPV/r	2	1.42
AZT/3TC/NVP→AZT/3TC/LPV/r	1	0.71
AZT/3TC/NVP→TDF/3TC/LPV/r	1	0.71
EFV → DTG	10	7.09
TDF/3TC/EFV→TDF/3TC/DTG	9	6.38
AZT/3TC/EFV→TDF/3TC/DTG	1	0.71
NVP → DTG	3	2.13
AZT/3TC/NVP→TDF/3TC/DTG	3	2.13
LPV/r → DTG	8	5.67
TDF/3TC/LPV/r→TDF/3TC/DTG	7	4.96
AZT/3TC/LPV/r→ TDF/3TC/DTG	1	0.71
Recommendations not followed	27	19.15
Changed to different regimen from recommendations	15	10.64
Continued the same regimen without following recommendations	12	8.51

ART, antiretroviral therapy; DR, drug resistance; EFV, Efavirenz; NVP, Nevirapine; LPV/r, Lopinavir/ritonavir; DTG, Dolutegravir; TDF, Tenofovir disoproxil fumarate; 3TC, Lamivudine; AZT, Zidovudine.

Table 3. Outcomes in different levels of hospitals by following recommendations (*n* = 141)

Level of hospital	Did not follow recommendations	Followed recommendations	Total	*p* value
Provincial hospitals				0.240
Not suppressed	4 (23.53)	7 (12.07)	11 (14.7)	
Suppressed	13 (76.47)	51 (87.93)	64 (85.3)	
District hospitals				0.032
Not suppressed	4 (40.00)	7 (12.50)	11 (16.7)	
Suppresse	6 (60.00)	49 (87.50)	55 (83.3)	

Not suppressed: VL ≥ 1,000 copies/mL; Suppressed: VL < 1,000 copies/mL. Data presented as *n* (%). *P* values from Pearson chi-square test.

Table 4. Univariate and multivariate logistic regression analyses of factors associated with viral load suppression (*n* = 141)

Characteristics	Crude OR (95% CI)	*P* value	Adjusted OR (95% CI)	*P* value
Following the recommendation				
No	1.0 (Reference)	-	1.0 (Reference)	-
Yes	3.01 (1.11– 8.16)	0.031	3.34 (1.13– 9.86)	0.029
Gender				
Male	1.0 (Reference)	-	1.0 (Reference)	-
Female	1.13 (0.43–2.98)	0.811	1.66 (0.56–4.93)	0.359
Age group				
< 25 years	1.0 (Reference)	-	1.0 (Reference)	-
25–34 years	0.94 (0.24–3.74)	0.935	0.70 (0.14–3.52)	0.667
35–44 years	2.62 (0.73–9.44)	0.141	2.22 (0.57–8.70)	0.253
45–54 years	2.78 (0.58–13.32)	0.202	2.57 (0.48–13.83)	0.272
≥ 55 years	0.94 (0.24–3.74)	0.935	0.70 (0.14–3.52)	0.667
Duration of HIV infection				
< 5 years	1.0 (Reference)	-	1.0 (Reference)	-
5–9 years	1.19 (0.37–3.84)	0.769	0.49 (0.04–6.51)	0.586
≥ 10 years	1.34 (0.47–3.82)	0.587	NA	0.994
Duration of ART				
< 1 year	1.0 (Reference)	-	1.0 (Reference)	-
1–4 years	1.06 (0.20–5.77)	0.945	1.00 (0.16–6.22)	0.999
5–9 years	1.50 (0.23–9.61)	0.669	1.92 (0.08–47.61)	0.689
≥ 10 years	1.27 (0.23–7.16)	0.787	NA	0.994
Hospital level				
District	1.0 (Reference)	-	1.0 (Reference)	-
Provincial	1.16 (0.47–2.89)	0.744	1.33 (0.46–3.87)	0.595

OR, odds ratio; CI, confidence interval; NA, not available due to perfect prediction. Model fit: Pearson χ^2 (59) = 49.91, p = 0.7944.

model was prominent in district-level healthcare facilities where HIV treatment experience, especially experience in managing ART failure, is still limited. Multivariate analysis confirmed that following the recommendations was the only significant factor associated with viral suppression (adjusted OR = 3.34). This supports existing evidence that affordable monitoring technologies are essential for ensuring the effectiveness of limited antiretroviral regimens in resource-limited settings (*5*).

Our study showed a viral suppression rate of 87.72% among patients following centralized DR testing recommendations, compared to 70.37% among those who did not. These results, achieved with a limited budget, are comparable to the following Vietnamese studies. A cross-sectional survey across four provinces found 93% viral suppression among patients on ART for at least one year (*13*). A Hanoi study showed suppression rates above 90% until 42 months on first-line ART (*14*), and research among drug users reported rates as low as 73% (*15*). Earlier evaluations in Ho Chi Minh City found 70% suppression, with viremia associated with prior ART exposure and immunologic failure (*16*). International research suggested that adherence support and prompt action on viral rebound might be more critical than resistance testing in some contexts (*17,18*). However, studies in resource-limited settings indicated that resistance testing improved care outcomes where treatment options were limited (*10*).

The results of our model demonstrated that centralized expertise guiding local treatment decisions significantly improved outcomes even with limited resources and treatment options. Therefore, our model offers a promising approach in Vietnam's evolving healthcare landscape to maximize effectiveness on a minimal budget. In traditional settings, most HIV diagnostic facilities have historically been centralized, requiring specialized infrastructure and trained staff, with laboratories often located far from patients' homes, resulting in high rates of loss to initiation and poor retention in care. This has prompted the need to find alternatives to traditional centralized laboratories, which paradoxically add more cost (*19*).

Our study is particularly timely as Vietnam navigates the challenging transition from international donor funding to domestic financing through SHI. International funding for HIV treatment and prevention has dramatically declined since Vietnam transitioned from a low-income to a lower-middle-income country in 2010, with estimates suggesting that available resources could fall from US$113 million in 2012 to just US$53 million by 2020 (*3,20,21*). This funding gap coincides with increased treatment needs. Mathematical models have projected that the number of people on ART in Vietnam will increase from approximately 98,000 in 2015 to 189,000 by 2030 (*3*). Our centralized-decentralized model offers a potential approach to maximize treatment effectiveness within these resource constraints.

Our findings have several important implications for HIV policy and practice in Vietnam and similar resource-limited settings. First, investment in centralized resistance testing infrastructure, paired with knowledge transfer to decentralized treatment sites, should be encouraged.

Second, the particular value of expert guidance for healthcare facilities with limited HIV treatment experience suggests that implementation should be prioritized for district-level hospitals. Third, meaningful improvements in treatment outcomes are achievable even within the constraints of Vietnam's transitioning financing landscape. These findings highlight the value of targeted interventions to reduce HIV drug resistance, when Vietnam scales up viral load testing and moves toward domestic financing of HIV services (*3,22*).

The study has several limitations. First, as a small pilot in selected healthcare facilities, our findings may not be fully generalizable across all settings in Vietnam. Second, the follow-up period was relatively short, and longer-term outcomes have yet to be evaluated. Third, we did not conduct a comprehensive economic analysis, which would be valuable for policy decisions regarding the nationwide implementation. Fourth, the study did not comprehensively analyze differences in adherence support strategies across study sites, nor did it assess patients' actual treatment adherence — both of which could have influenced treatment outcomes. Nevertheless, as all study sites were part of the public healthcare system, the potential for adherence-related bias may have been partially mitigated through the implementation of a standardized protocol issued by the Vietnam Ministry of Health (*11*). However, future studies should examine adherence-related factors more thoroughly to gain a deeper understanding of their impact on treatment effectiveness.

Future research should examine the cost-effectiveness of this approach within the SHI financing framework and explore adaptations to reach key populations who may face barriers to accessing facility-based care. The integration of point-of-care testing with centralized resistance monitoring could address the "total coverage model", which ensures access for the entire national population.

Conclusion

Our model in Northern Vietnam demonstrated significant clinical benefit with substantially higher viral suppression rates among patients who followed the recommendations. This effect was particularly pronounced in non-specialized HIV treatment centers. These findings support the expansion of our model to strengthen HIV treatment capacity across the whole country.

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Conflict of Interest: The authors have no conflicts of interest to disclose.

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