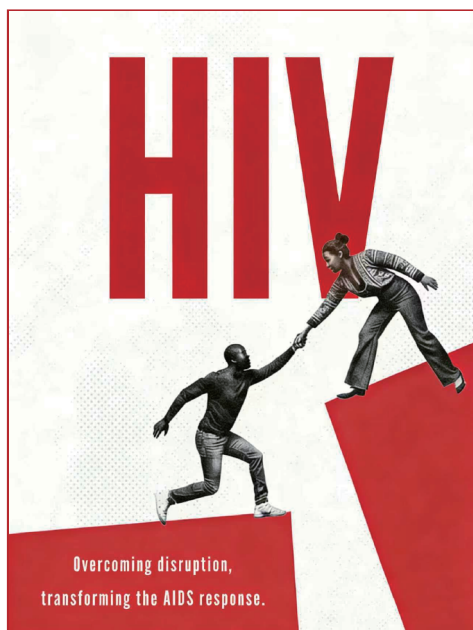


CHINA CDC WEEKLY



中国疾病预防控制中心周报 (英文)



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Preplanned Studies

Late HIV Diagnosis and Associated Factors Among Newly Reported HIV/AIDS Cases Aged ≥ 50 Years — China, 2022–2024

Duo Shan¹; Yalan Wang¹; Yuan Zhao¹; Chunpeng Zang¹; Juan Yang¹; Hui Li¹; Jiarong Ren¹;
Mengchi Liu¹; Yufen Liu^{1,†}

Summary

What is already known about this topic?

Late human immunodeficiency virus (HIV) diagnosis remains prevalent among older adults in China; however, recent national-level evidence characterizing its correlates remains limited.

What is added by this report?

Using nationwide surveillance data spanning 2022–2024 and employing two complementary analytical approaches, this study identified transmission route and geographic region as primary correlates of late HIV diagnosis. Decision-tree analysis further identified two distinct subgroups in eastern China exhibiting particularly elevated proportions of late diagnosis.

What are the implications for public health practice?

These findings provide epidemiological evidence to inform more targeted HIV screening strategies tailored to specific population subgroups, geographic regions, and diagnostic settings.

migrants, ethnic minorities, those without sexually transmitted disease (STD) history, individuals with higher education, cases diagnosed in medical institutions, residents of eastern China, and those infected through non-marital commercial heterosexual contact (adjusted odds ratio=1.05–1.60). The decision-tree model identified transmission route and region as primary stratifiers. Within the eastern China branch, two terminal subgroups exhibited particularly high proportions of late diagnosis: individuals infected through non-marital commercial heterosexual contact (74.6%) and those infected through other heterosexual or men who have sex with men (MSM) routes who were diagnosed in medical institutions (73.0%).

Conclusions: Late HIV diagnosis among older adults in China remains persistently high. These findings identify specific population subgroups and diagnostic settings with elevated proportions of late diagnosis and underscore the need for targeted screening interventions, strengthened testing protocols in medical settings, and enhanced risk awareness among older heterosexual adults.

ABSTRACT

Introduction: Late HIV diagnosis represents a critical public health challenge among older adults in China. Identifying its correlates is essential for enhancing timely detection and improving health outcomes.

Methods: We analyzed newly reported human immunodeficiency virus (HIV)-infected cases aged ≥ 50 years using national surveillance data from 2022–2024. Logistic regression was employed to examine factors associated with late diagnosis, while decision tree modeling captured complex variable interactions.

Results: Among 162,026 cases, 77.78% were diagnosed late. Late diagnosis was more frequently observed among males, older individuals, non-

Late human immunodeficiency virus (HIV) diagnosis remains a major global challenge, despite substantial progress in HIV prevention and treatment (1). The European Late Diagnosis Consensus Working Group (2) defines late HIV diagnosis as an initial HIV diagnosis with a CD4 count <350 cells/ μ L or the presence of an acquired immunodeficiency syndrome (AIDS)-defining event, regardless of CD4 level. This phenomenon is particularly prevalent among adults aged ≥ 50 years, who often underestimate their infection risk and may engage in high-risk sexual behaviors without seeking timely testing (3). Among older adults, late diagnosis leads to compromised immune recovery, increased susceptibility to

opportunistic infections, and elevated mortality. At the population level, delayed diagnosis undermines the public health benefits of Treatment as Prevention, increases healthcare expenditures, and heightens the risk of ongoing transmission (4). Although numerous studies have examined late HIV diagnosis, most have been regional or population-specific, leaving a gap in recent national-level evidence. Furthermore, prior national investigations have predominantly focused on individual risk factors without exploring interaction-based risk stratification among older adults. To address these limitations, we analyzed recent nationwide surveillance data from adults aged ≥ 50 years using a classification and regression tree (CRT) model. Our objectives were to identify high-risk subgroups through interaction-based analysis and to characterize factors associated with late diagnosis, thereby informing more targeted screening and intervention strategies.

Data were obtained from the Chinese HIV/AIDS Comprehensive Response Information Management System. Among newly reported cases from January 1, 2022 to December 31, 2024 with a final review status of “approved” and aged ≥ 50 years at diagnosis, late diagnosis was defined using five established criteria (5): 1) HIV/AIDS deaths from non-accidental causes; 2) surviving or accidental-death HIV/AIDS cases with CD4 count < 350 cells/ μL ; 3) surviving or accidental-death AIDS cases with CD4 count between 350–499 cells/ μL ; 4) surviving or accidental-death AIDS cases without CD4 testing; 5) surviving or accidental-death HIV cases without CD4 testing. For the fifth category, late diagnosis status was estimated based on the proportion of CD4 < 350 cells/ μL among tested cases within the same demographic stratum. Because this estimation approach could not be verified at the individual level and introduced potential measurement error, we excluded the fifth category from the multivariable analysis to ensure diagnostic accuracy.

Regions were grouped into eastern, central, and western zones according to economic development level. The variable ‘source of detection’ was included as a surveillance-based classification to capture differences in case-finding contexts. “Transmission route” was classified using standardized categories from the national HIV surveillance system at the time of case reporting. Variables were selected for analysis based on two criteria: their established relevance in prior surveillance-based studies of late HIV diagnosis and their availability within the national HIV surveillance system with standardized reporting protocols. Data

were cleaned using Excel 2021 (Microsoft Corporation, Redmond, Washington, USA) and analyzed in R version 4.2 (version 4.2, R Foundation for Statistical Computing, Vienna, Austria). Chi-square tests were used for group comparisons, and logistic regression was applied for both univariate and multivariate analyses. Adjusted odds ratios (*aORs*) and 95% confidence intervals (*CI*s) were calculated. Statistical significance was set at $P < 0.05$. A classification and regression tree (CRT) model was developed to predict late diagnosis using recursive binary splitting, which partitions data based on variables that maximize homogeneity within resulting subgroups (measured by reduction in Gini impurity, a metric quantifying classification accuracy). Data were randomly divided into training (70%) and validation (30%) sets, with cross-validation pruning applied to prevent overfitting. Variable importance was assessed by evaluating each variable’s split frequency and contribution to model performance, with region and transmission route emerging as key stratifiers.

A total of 162,026 newly reported HIV/AIDS cases aged ≥ 50 years were included in the analysis, of whom 71.13% were male (115,279/162,026). Overall, 77.78% (126,018/162,026) were diagnosed late. Demographic characteristics revealed that nearly half were aged 50–59 years (47.09%), 65.0% were farmers, and the majority were of Han ethnicity (87.93%), had education below primary school level (61.45%), and were married (57.10%). Geographically, eastern China accounted for 48.45% of all cases, and 96.19% were non-migrants. Heterosexual transmission was the predominant route (90.23%), with non-marital non-commercial contact representing the most common subtype (42.03%, 68,106/162,026). Most cases were identified through medical institutions (69.51%, 112,619/162,026).

After excluding individuals without CD4 results, 145,741 cases remained for multivariable analysis. Among these cases with complete CD4 data, 75.29% (109,733/145,741) were diagnosed late, a slightly lower proportion than the overall sample due to the exclusion of estimated late diagnoses without laboratory confirmation. Late diagnosis demonstrated positive associations with male sex (*aOR*=1.13), non-migration status (*aOR*=1.18), absence of STD history (*aOR*=1.11), higher educational attainment (*aOR*=1.08–1.10), and residence in eastern China (*aOR*=1.14). Weaker positive associations were observed for ethnic minority status (*aOR*=1.06) and

older age ($aOR=1.08-1.11$). Regarding transmission routes, non-marital commercial heterosexual contact exhibited the highest risk relative to injection drug use (IDU) ($aOR=1.60$, 95% CI : 1.25, 2.05). Cases detected in medical institutions also demonstrated elevated odds of late diagnosis compared with those identified through key population screening ($aOR=1.05$, 95% CI : 1.02, 1.08) (Table 1).

The decision-tree model identified transmission route, region, migration status, sex, and source of detection as the primary stratifiers of late diagnosis, yielding 14 terminal subgroups (referred to as “nodes” in tree-based classification). The overall proportion of late diagnosis at the root node was 67.7%. Following stratification by region, the model identified two particularly high-risk terminal nodes within the eastern China branch (Node 3). The first high-risk pathway comprised individuals in eastern China infected through non-marital commercial heterosexual contact (Node 7), with a late diagnosis proportion of 74.6%. The second high-risk pathway included individuals in eastern China infected through transmission from an HIV-positive spouse/regular partner, men who have sex with men (MSM), or non-marital non-commercial heterosexual contact, who were subsequently diagnosed in medical institutions (Node 11), with a late diagnosis proportion of 73.0% (Figure 1).

The logistic regression and decision-tree models demonstrated comparable overall discrimination, with AUCs of 0.710 (95% CI : 0.708–0.713) and 0.718 (95% CI : 0.715–0.721), respectively ($P<0.001$). However, the decision-tree model exhibited superior sensitivity (0.976 *vs.* 0.859) and a larger Youden index (0.451 *vs.* 0.326), indicating moderately better performance in identifying late diagnosis among adults aged ≥ 50 years (Figure 2).

DISCUSSION

Based on nationwide surveillance data from 2022 to 2024, a substantial proportion of adults aged ≥ 50 years were diagnosed at a late stage (77.78%), a rate that has remained persistently elevated compared with earlier reports in which late diagnosis consistently exceeded 65% during 2015–2019 (3). Although internal data suggested a temporary decline during 2020–2021, potentially attributable to coronavirus disease 2019 (COVID-19) pandemic-related disruptions in testing services, the persistently high proportion observed in recent years indicates that timely HIV diagnosis among

older adults continues to present significant challenges. Previous studies have generally demonstrated that late HIV diagnosis among older adults is associated with a range of demographic and epidemiological factors, including male sex, heterosexual transmission, and facility-based diagnosis, most often identified through logistic regression analyses (3,6). Consistent with this literature, our regression results confirmed similar associations. Through decision-tree modeling, we extended these findings by illustrating how such factors co-occur within the observed data. Beyond identifying independent associations, the decision-tree model delineated two high-risk terminal nodes in eastern China — non-marital commercial heterosexual transmission and other heterosexual or MSM transmission routes combined with diagnosis in medical institutions — thereby uncovering interaction-based risk patterns not captured by regression analysis alone.

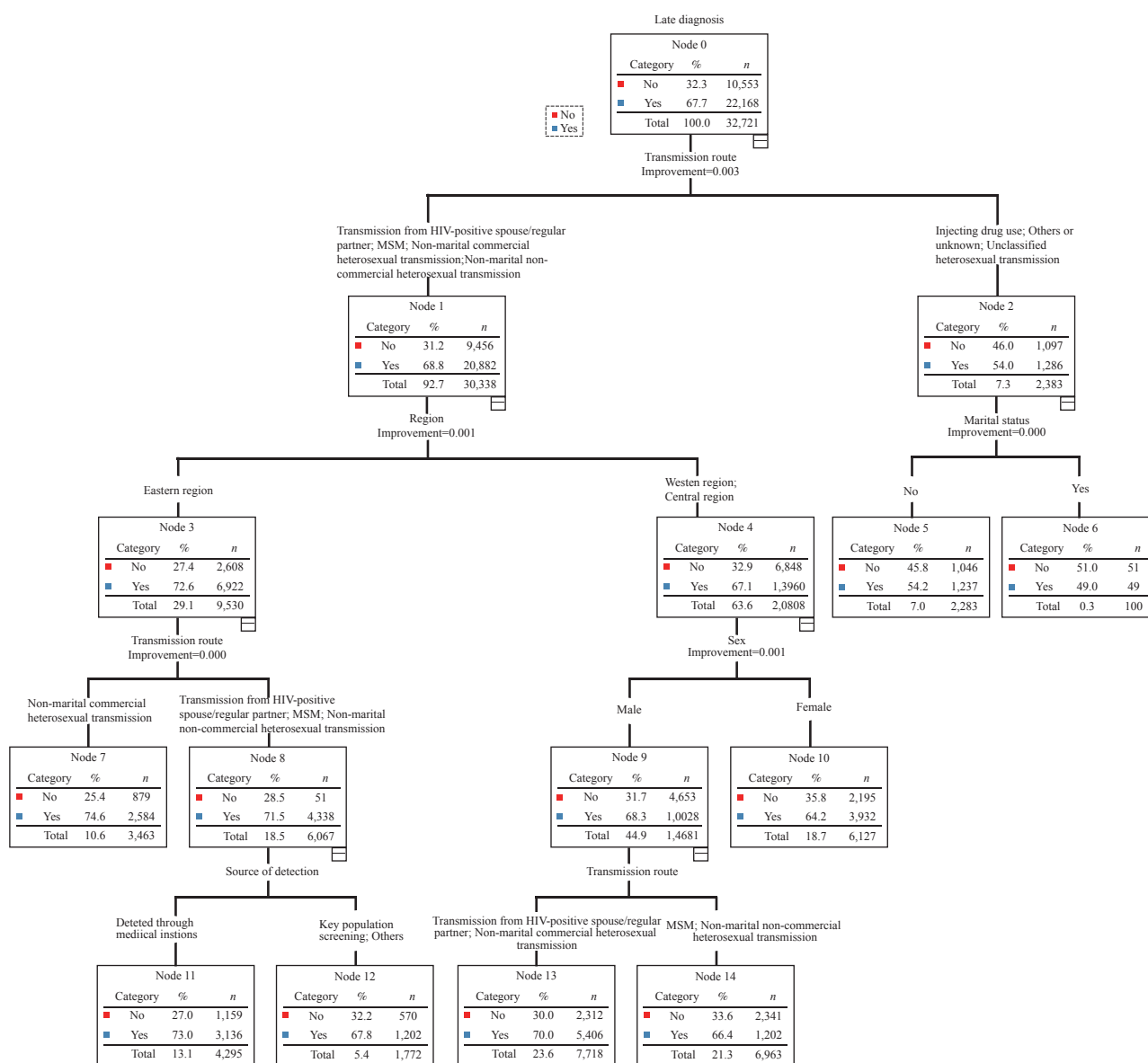
Notably, the eastern region exhibited the highest proportion of late diagnosis, contrasting with earlier studies that reported greater risks in southwestern China (7–8). This regional difference likely reflects variation in HIV service delivery pathways. Long-standing high-burden areas in the southwest have developed more established surveillance systems and proactive testing practices, whereas routine HIV screening remains less systematically integrated into outpatient care across many eastern settings (9). Additionally, a higher proportion of late diagnosis was observed among cases detected in medical institutions, suggesting persistent reliance on symptom-driven testing rather than routine screening protocols. Non-migrants demonstrated a higher proportion of late diagnosis, potentially reflecting reduced access to testing opportunities or support services. The variable “no history of sexually transmitted disease” showed only weak associations and did not emerge as a splitting variable in the decision-tree model, indicating limited contribution to risk stratification. While earlier studies predominantly identified individual-level factors such as sex, education, and transmission route (3,8), the decision-tree analysis in this study further delineated specific factor combinations — particularly heterosexual transmission in eastern regions combined with diagnosis in medical institutions — thereby providing a more nuanced characterization of heterogeneity in late diagnosis patterns.

This study has several limitations. First, reliance on case-reporting data without serological markers for

TABLE 1. Factors associated with late diagnosis among cases aged ≥ 50 years, 2022–2024 ($n=145,741$).

Variables	Late diagnosis		Multivariate analysis				
	N	Proportion (%)	β	S.E.	Z	P	aOR (95% CI)
Sex							
Female	30,393	70.51					1.00 (Reference)
Male	79,340	77.30	0.13	0.01	8.90	<0.05	1.13 (1.10, 1.16)
Age (years)							
50–59	50,996	76.08					1.00 (Reference)
60–69	35,961	80.54	0.10	0.01	8.28	<0.05	1.11 (1.08, 1.13)
70–79	19,092	78.34	0.08	0.02	5.15	<0.05	1.08 (1.05, 1.11)
≥ 80	3,684	73.34	0.03	0.03	-4.87	<0.05	0.87 (0.82, 0.92)
Migration status							
Yes	3,932	75.27					1.00 (Reference)
No	105,801	76.02	0.17	0.03	6.05	<0.05	1.18 (1.12, 1.25)
Occupation							
Farmer	71,656	75.64					1.00 (Reference)
Others	38,077	74.64	-0.03	0.01	-2.22	<0.05	0.97 (0.95, 0.99)
Ethnicity							
Han	96,299	74.31					1.00 (Reference)
Ethnic minorities	13,434	75.43	0.05	0.02	3.16	<0.05	1.06 (1.02, 1.09)
History of sexually transmitted diseases (STDs)							
Yes	14,126	75.08					1.00 (Reference)
No	87,098	75.35	0.10	0.02	6.63	<0.05	1.11 (1.08, 1.14)
Unknown	8,509	75.05	0.07	0.02	3.06	<0.05	1.08 (1.03, 1.13)
Education level							
Illiterate	12,952	74.08					1.00 (Reference)
Primary school	54,191	75.06	0.09	0.02	5.13	<0.05	1.09 (1.06, 1.13)
Junior high school	31,131	75.85	0.10	0.02	4.98	<0.05	1.10 (1.06, 1.14)
Senior high school or above	11,459	74.63	0.07	0.02	3.04	<0.05	1.08 (1.03, 1.13)
Source of detection							
Key population screening	21,291	71.75					1.00 (Reference)
Medical institutions	76,576	76.99	0.05	0.01	3.43	<0.05	1.05 (1.02, 1.08)
Others	11,866	71.49	-0.03	0.02	-1.26	0.207	0.97 (0.94, 1.01)
Regional distribution							
Western	51,944	74.12					1.00 (Reference)
Central	17,544	74.78	0.04	0.02	2.49	<0.05	1.06 (1.03, 1.09)
Eastern	40,245	76.49	0.13	0.01	10.38	<0.05	1.14 (1.11, 1.17)
Route of transmission							
Injecting drug use	157	72.59					1.00 (Reference)
Others or unknown	998	70.66	-0.26	0.13	-1.92	0.055	0.77 (0.59, 1.01)
Male-to-male sexual contact	9,407	73.42	0.33	0.13	2.63	<0.05	1.40 (1.09, 1.79)
Unclassified heterosexual transmission	5,451	71.04	-0.18	0.13	-1.40	0.161	0.84 (0.65, 1.07)
HIV-positive spouse or regular partner	8,747	75.21	0.37	0.13	2.91	<0.05	1.45 (1.13, 1.86)
Non-marital commercial heterosexual contact	39,201	77.92	0.47	0.13	3.73	<0.05	1.60 (1.25, 2.05)
Non-marital non-commercial heterosexual contact	45,772	74.81	0.34	0.13	2.72	<0.05	1.41 (1.10, 1.80)

Abbreviation: aOR=adjusted odds ratio; CI=confidence interval; S.E.=standard error; Z=Z statistic.

FIGURE 1. Decision tree model analysis results of late diagnosis aged ≥ 50 years, 2022–2024.

recent infection (e.g., limiting antigen avidity assays) may introduce misclassification bias in distinguishing recent from long-standing infections at the time of diagnosis. Although excluding estimated cases reduced measurement error, this approach may have also reduced statistical power and limited generalizability. Second, potential misclassification of sexual transmission categories may exist (10), as self-reported behavioral information is susceptible to recall bias and non-disclosure. Third, the cross-sectional design precludes causal inference. Furthermore, key behavioral, psychosocial, and healthcare access-related factors were not captured in the surveillance dataset and therefore could not be assessed. Despite these

limitations, the use of nationwide surveillance data and complementary analytic approaches strengthens the robustness of the findings. In conclusion, this study identified substantial heterogeneity in late HIV diagnosis among older adults in China, providing epidemiologically grounded evidence to inform targeted early testing strategies and prioritize interventions for high-risk subgroups.

Conflicts of interest: The authors declare no conflicts of interest.

Ethical statement: Approval by the Ethics Committee of the National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention (approval number:

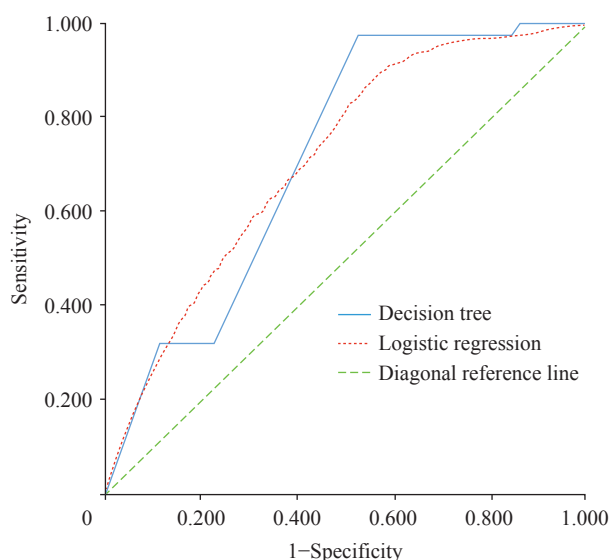


FIGURE 2. ROC curves comparing the predictive performance of the two models for late HIV diagnosis among adults aged ≥ 50 years, 2022–2024.

Abbreviation: ROC=receiver operating characteristic.

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Corresponding author: Yufen Liu, yufenliu69@chinaaids.cn.

¹ National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine, Beijing, China.

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Preplanned Studies

Impact of Hepatitis C Virus Co-infection on Antiretroviral Therapy Outcomes in Adults Living with HIV — China, 2002–2023

Decai Zhao^{1,✉}; Jingkun Hu^{2,✉}; Yan Zhao¹; Xiumin Gan¹; Fan Lyu^{1,✉}

Summary

What is already known about this topic?

The impact of hepatitis C virus (HCV) co-infection on antiretroviral therapy (ART) outcomes in people living with human immunodeficiency virus (HIV) remains controversial across studies.

What is added by this report?

Using stratified matching methods, we constructed two cohorts — one with HIV/HCV co-infection and one with HIV mono-infection — to compare ART outcomes. Our analysis revealed that HIV/HCV co-infected individuals faced significantly elevated risks of mortality, virological failure, and attrition relative to their HIV mono-infected counterparts.

What are the implications for public health practice?

Enhanced prevention, screening, and management (including treatment) of hepatitis C virus within people living with human immunodeficiency virus should be prioritized and strengthened as part of routine clinical care.

higher risk of mortality, virological failure, and attrition compared to HIV mono-infected individuals. The risks were highest for all ART outcomes in the group with a baseline CD4 count of 200–349 cells/μL.

Conclusion: Given the adverse impact of HCV co-infection on treatment outcomes among people living with HIV (PLWH), enhanced prevention, screening, and management (including treatment) of HCV within PLWH should be prioritized and strengthened as part of routine clinical care.

The epidemics of human immunodeficiency virus (HIV) and hepatitis C virus (HCV) continue to impose substantial disease burdens worldwide (1–2), with both viruses facing the goal of ending epidemics and eliminating public health threats by 2030 (3–4). Due to similar transmission pathways, people living with HIV (PLWH) are prone to co-infection with HCV (5–6). However, evidence regarding the impact of HCV co-infection on antiretroviral therapy (ART) outcomes in PLWH remains debated across studies (7–8), and high-quality evidence to guide clinical practice is lacking. To address this knowledge gap, we utilized nearly two decades of national ART data to investigate how HCV co-infection may influence ART outcomes in PLWH.

We conducted a retrospective cohort study using the National Free Antiretroviral Treatment Program database, with follow-up extending from ART initiation through December 31, 2023. This database provided comprehensive, long-term, real-world data that accurately captured the complete treatment trajectory for PLWH. Participant inclusion criteria were: 1) age ≥18 years; 2) HBsAg negative; 3) ART initiation before 2023; and 4) availability of baseline CD4 count. Participants were stratified by baseline CD4 count into four groups: 0–199, 200–349, 350–499, and ≥500 cells/μL. Within each stratum, we performed individual matching, pairing HIV/HCV co-

ABSTRACT

Introduction: Human immunodeficiency virus (HIV) and hepatitis C virus (HCV) represent two major public health threats worldwide. However, the impact of HCV co-infection on HIV antiretroviral therapy (ART) outcomes remains debated.

Methods: Using data from the National Free Antiretroviral Treatment Program database, we employed stratified matching methods to extract two cohorts: HIV/HCV co-infected individuals and HIV mono-infected individuals. We compared differences in their ART outcomes — mortality, virological failure, and attrition — through stratified Cox regression and conditional logistic regression analyses.

Results: A total of 10,953 HIV/HCV co-infected and 17,348 HIV mono-infected individuals were included. Across all baseline CD4 strata, HIV/HCV co-infected individuals demonstrated a significantly

infected individuals with HIV mono-infected individuals. To enhance study efficiency, we applied a 1:2 matching ratio for the CD4 count strata of 0–199 and 200–349 cells/ μ L; for the remaining two strata with relatively fewer participants, we adopted a 1:1 matching ratio. Based on previous research identifying major factors influencing HIV treatment outcomes, matching variables included sex, ART initiation date, ART initiation institution, ART regimen, and age (8–9) (Supplementary Figure S1, available at <https://weekly.chinacdc.cn/>). Unmatched individuals were excluded from the analysis. Due to limited availability of HCV-RNA data in the database, anti-HCV positivity served as the indicator of HCV infection in this study. Consequently, we were unable to distinguish between past and active HCV infection. We assessed three outcomes: mortality (all-cause mortality), virological failure (viral load >400 copies/mL after 6 months of ART), and attrition (including death, loss-to-follow-up, and treatment withdrawal). We evaluated the association between HCV seropositivity and both mortality and virological failure using stratified Cox regression models, while conditional logistic regression was applied to assess attrition due to its composite nature. Since major confounding factors influencing HIV treatment outcomes were controlled through stratification and matching, HCV status served as the sole covariate in both the Cox and logistic regression models. In sensitivity analyses, we redefined virological failure using different viral load thresholds (>50, >400, and >1,000 copies/mL) within the stratified Cox regression framework. All statistical analyses were performed using SAS software (version 9.4, SAS Institute Inc., Cary, NC, USA), with statistical significance defined as $P < 0.05$.

This study included 10,953 HIV/HCV co-infected and 17,348 HIV mono-infected individuals. The two groups demonstrated excellent comparability, with well-balanced distributions of sex, ART initiation date, ART initiation institution, ART regimen, and age across all baseline CD4 cell count strata (Table 1). Across all baseline CD4 strata, HIV/HCV co-infected individuals exhibited a higher proportion of adverse ART outcomes compared to HIV mono-infected individuals, and both Cox and logistic regression analyses confirm the significance of this difference (Supplementary Table S1, Figure 1). When comparing co-infected to mono-infected groups, the odds ratio for attrition was lowest in the ≥ 500 cells/ μ L stratum (1.42) and highest in the 200–349 cells/ μ L stratum (1.92).

Correspondingly, the hazard ratios for virological failure were 1.20 and 1.47, while those for death were 1.44 and 2.13, respectively. All differences achieved statistical significance (Figure 1). The effect size of HCV co-infection on ART outcomes varied substantially across baseline CD4 strata, with the highest risks for all outcomes observed in the group with baseline CD4 counts of 200–349 cells/ μ L.

Sensitivity analysis revealed a consistent pattern in which HCV co-infection remained associated with an increased risk of virological failure across subgroups. Hazard ratio values ranged from 1.10 to 1.47, with the exception of one subgroup characterized by a baseline CD4 count ≥ 500 cells/ μ L and a viral load threshold >50 copies/mL. The results achieved statistical significance in the remaining 11 subgroups (Figure 2).

DISCUSSION

This nationwide cohort study, spanning two decades and encompassing over 28,000 participants, demonstrates that HCV co-infection significantly increases the risks of death, virological failure, and attrition among PLWH. The elevated risk was most pronounced in individuals with baseline CD4 counts of 200–349 cells/ μ L. Our findings regarding mortality and attrition align with both domestic and international research. However, some studies have reported no significant difference in virological failure risk between HIV/HCV co-infected and HIV mono-infected individuals — discrepancies that may stem from variations in study populations, follow-up duration, and analytical approaches (8,10). The effect magnitude of HCV co-infection on treatment outcomes varied across baseline CD4 strata, with the strongest associations observed in the 200–349 cells/ μ L group. Furthermore, sensitivity analyses confirmed the robustness of the relationship between HCV co-infection and virological response, consistently demonstrating elevated failure risk among co-infected individuals across different viral load thresholds.

This study leverages large-scale real-world data from the nationwide ART database. Through rigorous study design, we employed stratification and matching methods to balance major confounding factors — rather than relying solely on statistical adjustments — and carefully selected eligible, high-quality data to construct two comparable observational cohorts. This methodology enables relatively precise estimation of the “net effect” of HCV co-infection on HIV treatment outcomes. Although observational studies

TABLE 1. Baseline characteristics of HIV/HCV co-infected and HIV mono-infected individuals by baseline CD4 count.

Baseline characteristics	Baseline CD4: 0–199 cells/ μ L		Baseline CD4: 200–349 cells/ μ L		Baseline CD4: 350–499 cells/ μ L		Baseline CD4: \geq 500 cells/ μ L	
	HIV/HCV (N=3,793, %)	HIV (N=7,586, %)	HIV/HCV (N=2,602, %)	HIV (N=5,204, %)	HIV/HCV (N=2,783, %)	HIV (N=2,783, %)	HIV/HCV (N=1,775, %)	HIV (N=1,775, %)
Gender								
Male	3,169 (83.5)	6,338 (83.5)	2,015 (77.4)	4,030 (77.4)	2,188 (78.6)	2,188 (78.6)	1,407 (79.3)	1,407 (79.3)
Female	624 (16.5)	1,248 (16.5)	587 (22.6)	1,174 (22.6)	595 (21.4)	595 (21.4)	368 (20.7)	368 (20.7)
Initial ART age (IQR)	40.6 (35.1, 46.7)	40.7 (35.2, 46.8)	37.7 (31.8, 44.2)	37.8 (31.8, 44.2)	36.2 (31.1, 42.3)	36.2 (30.8, 42.5)	35.2 (30.0, 41.1)	35.3 (29.9, 41.0)
Initial ART sites								
General hospitals	1,665 (43.9)	3,330 (43.9)	1,442 (55.4)	2,884 (55.4)	1,876 (67.4)	1,876 (67.4)	1,286 (72.5)	1,286 (72.5)
Infectious disease hospitals	1,798 (47.4)	3,596 (47.4)	977 (37.5)	1,954 (37.5)	628 (22.6)	628 (22.6)	318 (17.9)	318 (17.9)
Community clinics	47 (1.2)	94 (1.2)	51 (2.0)	102 (2.0)	109 (3.9)	109 (3.9)	77 (4.3)	77 (4.3)
Other sites	283 (7.5)	566 (7.5)	132 (5.1)	264 (5.1)	170 (6.1)	170 (6.1)	94 (5.3)	94 (5.3)
Initial ART date								
2002–2009	95 (2.5)	190 (2.5)	49 (1.9)	98 (1.9)	–	–	–	–
2010–2014	1,411 (37.2)	2,822 (37.2)	976 (37.5)	1,952 (37.5)	884 (31.8)	884 (31.8)	449 (25.3)	449 (25.3)
2015–2019	1,657 (43.7)	3,314 (43.7)	1,220 (46.9)	2,440 (46.9)	1,511 (54.3)	1,511 (54.3)	1,074 (60.5)	1,074 (60.5)
2020–2022	630 (16.6)	1,260 (16.6)	357 (13.7)	714 (13.7)	388 (13.9)	388 (13.9)	252 (14.2)	252 (14.2)
Initial ART regimens								
AZT/D4T+3TC+NVP/EFV	930 (24.5)	1,860 (24.5)	693 (26.6)	1,386 (26.6)	495 (17.8)	495 (17.8)	184 (10.4)	184 (10.4)
TDF+3TC+NVP/EFV	2,691 (70.9)	5,382 (70.9)	1,858 (71.4)	3,716 (71.4)	2,208 (79.3)	2,208 (79.3)	1,519 (85.6)	1,519 (85.6)
AZT/TDF+3TC+DTG/LPV/r	87 (2.3)	174 (2.3)	32 (1.2)	64 (1.2)	62 (2.2)	62 (2.2)	57 (3.2)	57 (3.2)
Other regimens	85 (2.2)	170 (2.2)	19 (0.7)	38 (0.7)	18 (0.6)	18 (0.6)	15 (0.8)	15 (0.8)

Abbreviation: HIV=human immunodeficiency virus; HCV=hepatitis C virus; CD4=cluster of differentiation 4 T-lymphocyte; ART=antiretroviral therapy; IQR=interquartile range; AZT=zidovudine; D4T=stavudine; 3TC=lamivudine; NVP=nevirapine; EFV=efavirenz; TDF=dolutegravir; LPV/r=lopinavir/ritonavir.

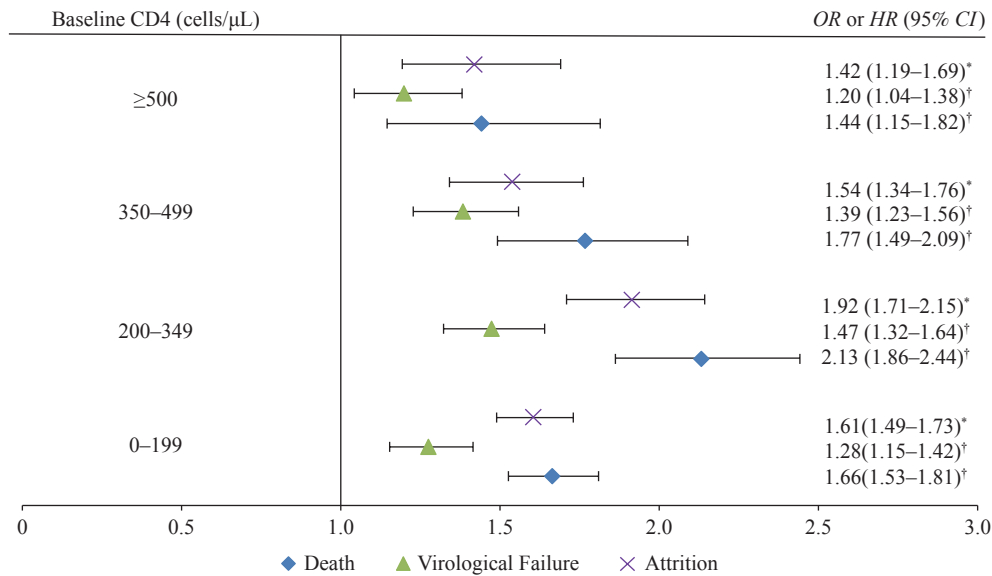


FIGURE 1. Impact of hepatitis C virus co-infection on antiretroviral therapy outcomes in people living with HIV. Abbreviation: OR=odds ratio; HR=hazard ratio; CD4=cluster of differentiation 4 T-lymphocyte; HIV=human immunodeficiency virus.

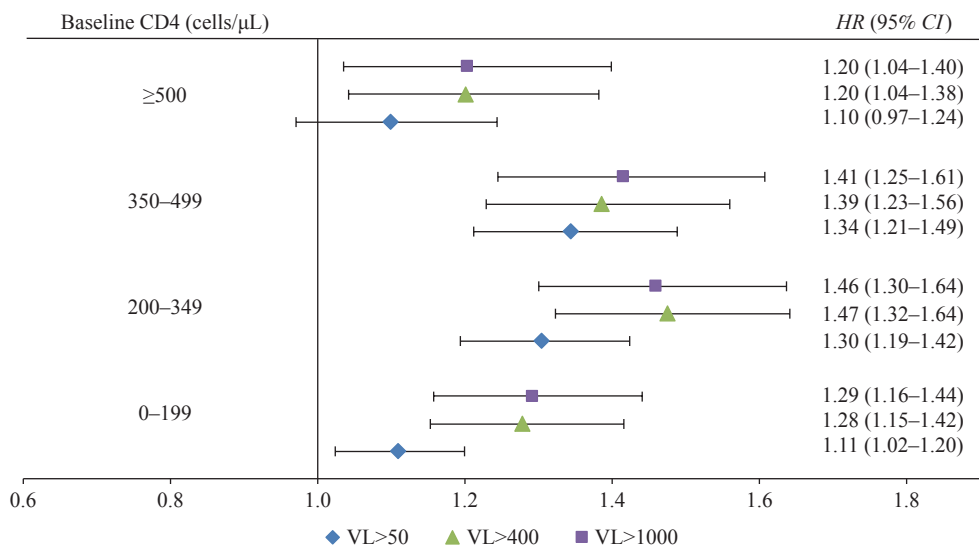


FIGURE 2. Sensitivity analysis of hepatitis C virus co-infection on virological failure in people living with HIV. Abbreviation: VL=HIV viral load; HR=hazard ratio; CD4=cluster of differentiation 4 T-lymphocyte; HIV=human immunodeficiency virus.

cannot control all potential confounders with the same rigor as a two-arm randomized controlled trial (RCT), our approach represents an innovative strategy to enhance research efficiency by controlling major confounders through thoughtful study design. This is particularly valuable given that conducting an RCT to evaluate the impact of HCV co-infection on HIV outcomes would be neither ethical nor feasible.

Several limitations warrant consideration. First, the absence of HCV-RNA testing data prevented us from

distinguishing between active and resolved HCV infections. Anti-HCV positivity, which encompasses both HCV-RNA negative and HCV-RNA positive individuals, may attenuate the observed impact of active HCV infection on adverse ART outcomes. Second, HCV treatment status can influence HIV treatment outcomes, but we were unable to analyze this variable due to its absence from our database. Third, as a retrospective observational study, we could not control for all possible residual confounders (e.g.,

tuberculosis co-infection, liver disease severity, socioeconomic factors). Nevertheless, by employing stratification and matching in our study design, we successfully controlled for major confounding factors. In the absence of available RCTs, this study represents a valuable contribution to understanding HCV's impact on HIV treatment outcomes.

In conclusion, given the substantial negative impact of hepatitis C virus co-infection on antiretroviral therapy outcomes among people living with human immunodeficiency virus, enhanced prevention, screening, and comprehensive management (including treatment) of hepatitis C virus infection within this population should be prioritized and strengthened as an integral component of routine clinical care.

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Ethical statement: Approved by the Institutional Review Board of the National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention (X191030594).

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Corresponding author: Fan Lyu, fanlv@chinaaids.cn.

¹ National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine, Beijing, China; ² Shanghai Institute of Infectious Disease and Biosecurity, Fudan University, Shanghai, China.

[✉] Joint first authors.

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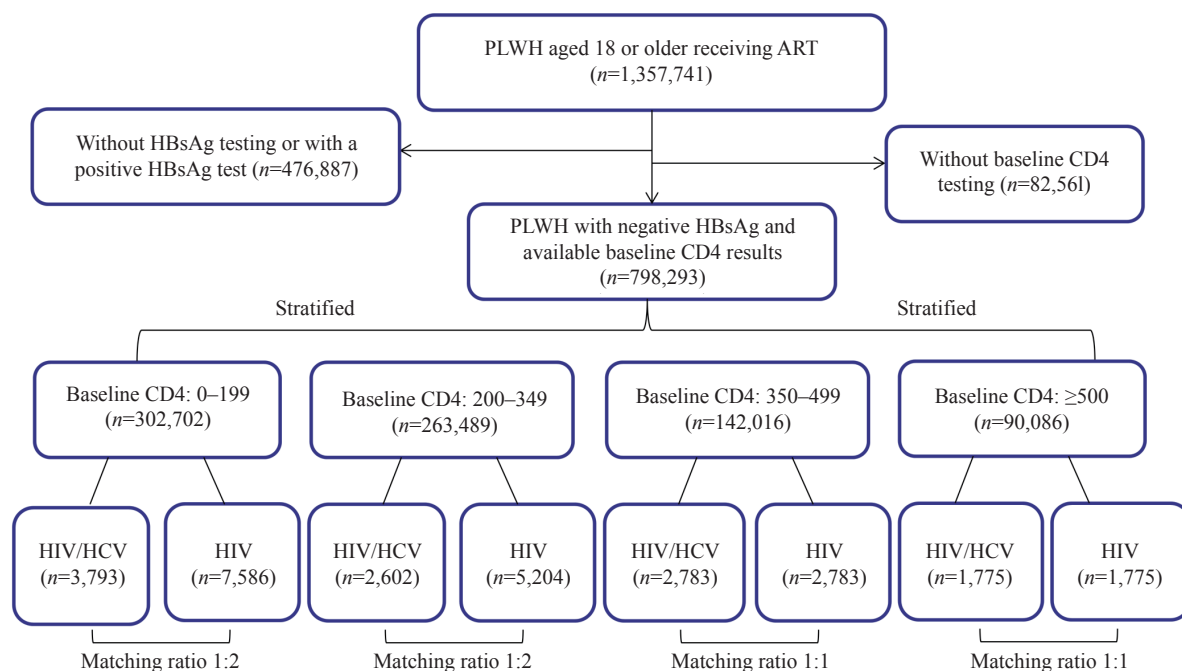
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SUPPLEMENTARY MATERIAL



SUPPLEMENTARY FIGURE S1. Introduction of sampling steps.

Note: Matching variables included sex, ART initiation date, ART initiation site, ART regimen, and age.

Abbreviation: PLWH=people living with human immunodeficiency virus; ART=antiretroviral therapy; HBsAg=hepatitis B surface antigen; CD4=cluster of differentiation 4 T-lymphocyte; HIV=human immunodeficiency virus; HCV=hepatitis C virus.

SUPPLEMENTARY TABLE S1. Antiretroviral therapy outcomes of HIV/HCV co-infected and HIV mono-infected individuals by baseline CD4 count.

ART outcomes	Baseline CD4: 0-199 cells/ μ L		Baseline CD4: 200-349 cells/ μ L		Baseline CD4: 350-499 cells/ μ L		Baseline CD4: ≥500 cells/ μ L	
	HIV/HCV (N=3,793, %)	HIV (N=7,586, %)	HIV/HCV (N=2,602, %)	HIV (N=5,204, %)	HIV/HCV (N=2,783, %)	HIV (N=2,783, %)	HIV/HCV (N=1,775, %)	HIV (N=1,775, %)
ART Status								
Retention	2,587 (68.2)	6,084 (80.2)	2,014 (77.4)	4,590 (88.2)	2,257 (81.1)	2,441 (87.7)	1,471 (82.9)	1,561 (87.9)
Loss to follow-up	70 (1.8)	83 (1.1)	74 (2.8)	97 (1.9)	68 (2.4)	65 (2.3)	59 (3.3)	49 (2.8)
Withdrawal	46 (1.2)	48 (0.6)	36 (1.4)	42 (0.8)	50 (1.8)	34 (1.2)	42 (2.4)	32 (1.8)
Death	1,090 (28.7)	1,371 (18.1)	478 (18.4)	475 (9.1)	408 (14.7)	243 (8.7)	203 (11.4)	133 (7.5)
Virological failure								
No	2,419 (63.8)	5,439 (71.7)	1,687 (64.8)	3,858 (74.1)	1,695 (60.9)	1,916 (68.8)	1,022 (57.6)	1,160 (65.4)
Yes	783 (20.6)	1,324 (17.5)	707 (27.2)	1,121 (21.5)	901 (32.4)	727 (26.1)	633 (35.7)	523 (29.5)
VL missing	591 (15.6)	823 (10.8)	208 (8.0)	225 (4.3)	187 (6.7)	140 (5.0)	120 (6.8)	92 (5.2)

Abbreviation: HIV=human immunodeficiency virus; HCV=hepatitis C virus; ART=antiretroviral therapy; CD4=cluster of differentiation 4 T-lymphocyte; VL=HIV viral load.

Preplanned Studies

Increasing Uptake of Pre-Exposure Prophylaxis and Associated Behavioral Changes Among Men Who Have Sex with Men — Qingdao City, Shandong Province, China, 2024–2025

Ruzhuo Liu¹; Peilong Li¹; Lin Ge¹; Meizhen Liao²; Xin Song³; Yong Fu³; Houlin Tang¹; Dongmin Li^{1,*}

Summary

What is already known on this topic?

Pre-exposure prophylaxis (PrEP) effectively prevents human immunodeficiency virus (HIV) infection among men who have sex with men (MSM); however, its uptake in China remains low.

What is added by this report?

In a prospective cohort of MSM in Qingdao, recent PrEP use doubled from 4.6% in June 2024 to 10.4% in June 2025, which was accompanied by decreased condomless anal intercourse and increased HIV testing. MSM who seek sexual partners online are less likely to use PrEP.

What are the implications for public health practice?

Public health strategies should prioritize targeted digital interventions for MSM who primarily seek sexual partners online, reinforce health education on the benefits of PrEP, and institutionalize PrEP referral pathways to accelerate PrEP scale-up.

10.4% in June 2025, which was accompanied by decrease in condomless anal intercourse and an increase in human immunodeficiency virus testing. The multivariate analysis revealed that MSM who primarily sought sexual partners online were less likely to use PrEP [adjusted odds ratio (*aOR*)=0.32, 95% confidence interval (*CI*): 0.15, 0.67], whereas perceived PrEP effectiveness (*aOR*=7.43, 95% *CI*: 3.29, 16.81) and prior post-exposure prophylaxis (PEP) use (*aOR*=2.20, 95% *CI*: 1.28, 3.71) were strong predictors of uptake.

Conclusion: PrEP uptake is increasing among MSM in Qingdao, complemented by positive shifts in sexual health behaviors. Public health strategies must prioritize innovative digital interventions to reach MSM who are active online, reinforce the benefits of PrEP, and institutionalize the PEP-to-PrEP pathways.

ABSTRACT

Introduction: Pre-exposure prophylaxis (PrEP) coverage among men who have sex with men (MSM) in China is suboptimal, and longitudinal data on uptake dynamics are scarce. This study describes temporal trends in PrEP use and identifies correlates of recent uptake among MSM in Qingdao, China.

Methods: Prospective cohort study conducted on MSM in Qingdao. Participants were enrolled between January 2024 and June 2024, with follow-up surveys conducted every six months until June 2025. The primary outcome was PrEP use in the past six months. Cochran–Armitage tests and generalized estimating equations were used for analysis.

Results: Among 580 MSM enrolled at baseline, 518 (89.3%) completed all follow-up visits. In this sample, recent PrEP use doubled from 4.6% in June 2024 to

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral medication against the human immunodeficiency virus (HIV), and it has been proven to be highly effective in diverse populations. As a critical component of combination HIV prevention, PrEP is instrumental in achieving the Joint United Nations Program on HIV/AIDS (UNAIDS)’s “95-95-95” targets to end the HIV epidemic. However, PrEP coverage among men who have sex with men (MSM) remains suboptimal in China, despite increasing policy attention and pilot implementation (1). Previous studies have relied mainly on cross-sectional designs and “ever used” metrics that obscure temporal patterns of engagement. To address this gap, we used longitudinal data to characterize the dynamic changes in PrEP use and identify its correlates among MSM in Qingdao, Shandong Province, China.

We conducted a prospective cohort study among MSM in Qingdao to analyze the temporal trends in PrEP use and identify the key factors influencing

recent uptake. Participants were recruited using snowball sampling through community-based organizations (CBOs) between January and June 2024. Eligible participants were HIV-negative, aged ≥ 18 years, and reported having sex with a man in the past six months. Following a baseline survey, participants were followed up every six months, and the final visit was completed in June 2025. Data on sociodemographics, risk behaviors, and healthcare utilization were collected via face-to-face interviews using structured questionnaires. Data entry was performed using the EpiData software (version 3.1, EpiData Assoc., Odense, Denmark). The primary outcome of interest was “recent PrEP use”, which is defined as self-reported use in the six months preceding the survey. In addition, “ever used” was defined as any use of PrEP at any point up to the survey date. Reporting was consistent with the STROBE checklist. This study was approved by the Ethics Committee of the National Center for AIDS/STD Control and Prevention and the Chinese Center for Disease Control and Prevention (Approval No. X151113388, dated June 18, 2024), and conformed to the ethical principles of the Declaration of Helsinki (2024). Written informed consent was obtained from all participants before enrollment.

Temporal trends in PrEP use and related behaviors were analyzed using the Cochran-Armitage test, and correlates of recent PrEP use were identified using generalized estimating equations (GEE). The model included a study visit to explicitly model the time trend. Other covariates selected based on univariate analyses ($P \leq 0.2$) were also included to identify independent predictors of recent PrEP use. A sensitivity analysis was performed to assess the potential impact of attrition bias, which included all baseline participants and all available follow-up data. All analyses were performed in SAS (version 9.4, SAS Institute Inc., Cary, NC, USA), and a P -value of ≤ 0.05 (two-tailed) was considered statistically significant.

A total of 580 MSM were enrolled at baseline, of which 518 (89.3%) completed all follow-up visits and were included in the primary analysis. Participants were predominantly aged ≥ 30 years (71.0%), highly educated (79.0% college graduates or above), and sexually active, with 87.1% reporting three or more casual partners in the past six months at baseline. More than two-thirds (66.7%) perceived PrEP to be effective, and 20.9% had previously used PEP (Table 1).

The percentage of the study group reported to have

ever used PrEP increased from 8.7% at baseline to 19.3% by June 2025, whereas the group who reported recent PrEP use doubled from 4.6% to 10.4%. In the same period, the prevalence of condomless anal intercourse (CAI) decreased (from 97.1% to 90.0%), while the proportion reporting frequent HIV testing (≥ 3 times in the past six months) increased significantly (from 85.7% to 93.1%) (Table 2).

The multivariate GEE model revealed that after accounting for covariates, recent PrEP use was significantly higher at the 12-month follow-up compared to baseline [adjusted odds ratio (*aOR*)=1.76, 95% confidence interval (*CI*): 1.15, 2.69], while no significant change was observed at six months. Several factors were independently associated with PrEP uptake. Participants who perceived PrEP to be effective (*aOR*=7.43, 95% *CI*: 3.29, 16.81) and those with a history of PEP use (*aOR*=2.20, 95% *CI*: 1.28, 3.71) were significantly more likely to report recent PrEP use. In contrast, MSM who primarily sought sexual partners online had significantly lower odds of using PrEP recently compared to those who sought partners offline (*aOR*=0.32, 95% *CI*: 0.15, 0.67) (Table 3).

A sensitivity analysis that included all 580 baseline participants yielded findings consistent with the primary analysis. The temporal trends in PrEP uptake (e.g., recent PrEP use increased from 4.5% to 10.4%), CAI, and HIV testing remained significant. Similarly, the multivariate GEE model identified the same four factors — study visit, perceived PrEP effectiveness, prior PEP use, and seeking sexual partners online — as significant correlates of recent PrEP use with comparable effect sizes.

DISCUSSION

This report on a prospective cohort in Qingdao provides crucial longitudinal evidence of the evolving landscape of PrEP use among Chinese MSM. The modest but steady increase in PrEP engagement was a positive signal, suggesting that ongoing promotional efforts have been successful. The proportion of the study group reporting an “ever used” rate of 19.3% is comparable to that of a recent multi-city online survey in China (17.9%) and higher than the rates reported in Shandong Province (9.2%) and Beijing (12.9%) (2–4). Nevertheless, these rates remain well below those seen in high-income countries, where uptake can exceed 40%, and are still below rates in some Latin American settings, such as Brazil (19.5%), indicating substantial room for programmatic expansion (5–6).

TABLE 1. Baseline characteristics of MSM participating in the PrEP in Qingdao (January–June 2024).

Variables	Participants	Follow-up	Lost to Follow-up	χ^2	P
	N=580	N ₁ =518 (89.3%)	N ₂ =62 (10.7%)		
Age, years					
18–29	168 (29.0)	155 (29.9)	13 (21.0)	2.15	0.142
≥30	412 (71.0)	363 (70.1)	49 (79.0)		
Marital status					
Single	449 (77.4)	396 (76.5)	53 (85.5)	2.59	0.108
Married	131 (22.6)	122 (23.5)	9 (14.5)		
Education level					
High school graduates or below	122 (21.0)	115 (22.2)	7 (11.3)	3.97	0.046
College graduates or above	458 (79.0)	403 (77.8)	55 (88.7)		
Monthly income, CNY					
<5,000	263 (45.3)	244 (47.1)	19 (30.7)	6.05	0.014
≥5,000	317 (54.7)	274 (52.9)	43 (69.3)		
Avenues for seeking sexual partners					
Offline	23 (4.0)	23 (4.4)	0 (0)	2.97	0.090
Online	557 (96.0)	495 (95.6)	62 (100)		
HIV infection risk perception					
Low/Moderate	565 (97.4)	506 (97.7)	59 (95.2)	1.40	0.237
High	15 (2.6)	12 (2.3)	3 (4.8)		
Sexual partners' HIV serostatus					
Negative	426 (73.4)	382 (73.7)	44 (71.0)	0.219	0.640
Unknown/Positive	154 (26.6)	136 (26.3)	18 (29.0)		
Recreational drug usage in the past six months					
No	148 (25.5)	126 (24.3)	9 (14.5)	2.98	0.084
Yes	445 (76.7)	392 (75.7)	53 (85.5)		
CAI in the past six months					
No	18 (3.1)	15 (2.9)	3 (4.8)	0.70	0.404
Yes	562 (96.9)	503 (97.1)	59 (95.2)		
Number of casual sexual partners in the past six months					
<3	75 (12.9)	64 (12.4)	11 (17.7)	1.43	0.232
≥3	505 (87.1)	454 (87.6)	51 (82.3)		
Commercial sex in the past six months					
No	466 (80.3)	409 (79.0)	57 (91.9)	5.90	0.016
Yes	114 (19.7)	109 (21.0)	5 (8.1)		
Group sex in the past six months					
No	113 (19.5)	103 (19.9)	10 (16.1)	0.497	0.480
Yes	467 (80.5)	415 (80.1)	52 (83.9)		
STIs in the past six months					
No	565 (97.4)	506 (97.7)	59 (95.2)	1.40	0.237
Yes	15 (2.6)	12 (2.3)	3 (4.8)		
Perceived PrEP effectiveness					
Not good	193 (33.3)	175 (33.8)	18 (29.0)	0.56	0.453
Good	387 (66.7)	343 (66.2)	44 (71.0)		

Continued

Variables	Participants	Follow-up	Lost to Follow-up	χ^2	P
	$N=580$	$N_1=518$ (89.3%)	$N_2=62$ (10.7%)		
Number of HIV testing in the past six months					
<3	83 (14.3)	74 (14.3)	9 (14.5)	0.01	0.961
≥ 3	497 (85.7)	444 (85.7)	53 (85.5)		
Ever used PEP					
No	459 (79.1)	411 (79.3)	48 (77.4)	0.12	0.724
Yes	121 (20.9)	107 (20.7)	14 (22.6)		

Note: $P \leq 0.05$ were considered statistically significant and are shown in bold.
Abbreviation: PrEP=pre-exposure prophylaxis; PEP=post-exposure prophylaxis; CAI=condomless anal intercourse; STIs=sexually transmitted infections; CNY=Chinese Yuan.

TABLE 2. Temporal trends of PrEP use and related behaviors among MSM in Qingdao (2024–2025).

Variables	Baseline (2024/06)	6-month follow-up (2024/12)	12-month follow-up (2025/06)	Z_{trend}	<i>P</i>
Ever used PrEP	45 (8.7)	60 (11.6)	100 (19.3)	5.05	<0.001
Recent PrEP use	24 (4.6)	30 (5.8)	54 (10.4)	3.67	<0.001
Recent PEP use	16 (3.1)	12 (2.3)	15 (2.9)	−0.19	0.850
Sexual partners who are HIV-positive or of unknown status in the past six months	136 (26.3)	96 (18.5)	134 (25.8)	−0.15	0.884
Recreational drug use in the past six months	392 (75.7)	398 (76.8)	386 (74.5)	−0.43	0.664
CAI in the past six months	503 (97.1)	507 (97.9)	466 (90.0)	−5.26	<0.001
Number of casual partners ≥3 in the past six months	454 (87.6)	461 (89.0)	452 (87.3)	−0.19	0.848
Engagement in commercial sex in the past six months	109 (21.0)	105 (20.3)	99 (19.1)	−0.77	0.438
Participation in group sex in the past six months	415 (80.1)	426 (82.2)	410 (79.1)	−0.39	0.695
Diagnosis of STIs in the past six months	12 (2.3)	16 (3.1)	7 (1.3)	−1.05	0.295
Frequent HIV testing (≥3) in the past six months	444 (85.7)	479 (92.5)	482 (93.1)	4.01	<0.001

Note: $P \leq 0.05$ were considered statistically significant and are shown in bold.
Abbreviation: PrEP=pre-exposure prophylaxis; PEP=post-exposure prophylaxis; CAI=condomless anal intercourse; STIs=sexually transmitted infections.

Notably, the simultaneous reduction in CAI and increase in HIV testing contradict concerns about “risk compensation” (7). Instead, the observed pattern suggests that PrEP engagement may encourage greater overall health-seeking behaviors. MSM who initiate PrEP are more likely to be health-conscious, motivated to test regularly, and engaged in community prevention services. Although PrEP users exhibit more positive health behaviors, it is still necessary to integrate these in interventions targeting the MSM populations. For instance, PrEP use should be combined with safer sexual practices (e.g., correct condom use) to form a dual protection model. Interventions, such as this “PrEP + safer sex” model, will further improve the effectiveness of HIV prevention and control and reduce the risk of other sexually transmitted infections (STIs).

The strong association between perceived PrEP effectiveness and uptake highlights the importance of

accurate, persuasive health communication, aligning with core tenets of behavioral theories, such as Protection Motivation Theory, where the perceived efficacy of a preventive action is a primary driver of behavior change (8). Equally important is the “PEP-to-PrEP” transition. Individuals who have previously used PEP often have a repeated risk of HIV exposure. Their experience with antiretroviral medications provides them with familiarity in adherence routines and healthcare engagement, making them ideal candidates for PrEP initiation (9). Therefore, multichannel health education should be conducted to clearly convey the high effectiveness of PrEP and correct cognitive biases. In particular, in PEP outpatient services, PrEP publicity and education should be provided simultaneously to individuals seeking consultation. Combined with an assessment of exposure risk, PrEP should be proactively recommended to build a seamless “PEP-to-PrEP” intervention pathway.

TABLE 3. Factors associated with recent PrEP use identified by GEE among MSM in Qingdao (2024–2025).

Variables	Recent PrEP use		OR (95% CI)	P	aOR (95% CI)	P
	No (N ₁ =1,446)	Yes (N ₂ =108)				
Age, years						
18–29	388 (93.0)	29 (7.0)	1.00			
≥30	1,058 (93.1)	79 (6.9)	0.98 (0.60, 1.59)	0.935		
Marital status						
Single	1,107 (92.4)	91 (7.6)	1.00		1.00	
Married	339 (95.2)	17 (4.8)	0.59 (0.32, 1.11)	0.103	0.67 (0.36, 1.27)	0.218
Education level						
High school graduate or below	324 (93.9)	21 (6.1)	1.00			
College graduate or above	1,122 (92.8)	87 (7.2)	1.19 (0.66, 2.15)	0.562		
Monthly income, CNY						
<5,000	689 (93.7)	46 (6.3)	1.00			
≥5,000	757 (92.4)	62 (7.6)	1.16 (0.71, 1.91)	0.553		
Avenues for seeking sexual partners						
Offline	63 (85.1)	11 (14.9)	1.00		1.00	
Online	1,383 (93.4)	97 (6.6)	0.33 (0.18, 0.63)	<0.001	0.32 (0.15, 0.67)	0.002
HIV infection risk perception						
Low/moderate	1,420 (93.3)	102 (6.7)	1.00		1.00	
High	26 (81.2)	6 (18.8)	3.40 (1.06, 10.86)	0.038	2.99 (0.96, 9.33)	0.059
Sexual partners' HIV serostatus						
Negative	1,109 (93.3)	79 (6.7)	1.00			
Unknown/positive	337 (92.1)	29 (7.9)	1.30 (0.78, 2.16)	0.318		
Recreational drug usage in the past six months						
No	352 (93.1)	26 (6.9)	1.00			
Yes	1,094 (93.0)	82 (7.0)	0.93 (0.55, 1.58)	0.791		
CAI in the past six months						
No	75 (96.1)	3 (3.9)	1.00			
Yes	1,371 (92.9)	105 (7.1)	1.65 (0.54, 5.02)	0.381		
Number of casual sexual partners in the past six months						
<3	177 (94.6)	10 (5.4)	1.00			
≥3	1,269 (92.8)	98 (7.2)	1.16 (0.62, 2.16)	0.646		
Commercial sex in the past six months						
No	1,154 (93.0)	87 (7.0)	1.00			
Yes	292 (93.3)	21 (6.7)	0.96 (0.51, 1.81)	0.908		
Group sex in the past six months						
No	286 (94.4)	17 (5.6)	1.00			
Yes	1,160 (92.7)	91 (7.3)	1.09 (0.65, 1.81)	0.745		
STIs in the past six months						
No	1,413 (93.0)	106 (7.0)	1.00			
Yes	33 (94.3)	3 (5.7)	0.87 (0.23, 3.29)	0.840		
Perceived PrEP effectiveness						
Not good	472 (98.7)	6 (1.3)	1.00		1.00	
Good	974 (90.5)	102 (9.5)	7.34 (3.12, 17.25)	<0.001	7.43 (3.29, 16.81)	<0.001

Continued

Variables	Recent PrEP use		OR (95% CI)	P	aOR (95% CI)	P
	No (N ₁ =1,446)	Yes (N ₂ =108)				
Number of HIV testing in the past six months						
<3	145 (97.3)	4 (2.7)	1.00		1.00	
≥3	1,301 (92.6)	104 (7.4)	3.13 (0.77, 12.68)	0.109	2.86 (0.77, 10.62)	0.117
Ever used PEP						
No	1,172 (94.4)	69 (5.6)	1.00		1.00	
Yes	274 (87.5)	39 (12.5)	2.28 (1.33, 3.91)	0.003	2.20 (1.28, 3.80)	0.005
Study visit						
Baseline (2024/06)	494 (95.4)	24 (4.6)	1.00			
6-month follow-up (2024/12)	488 (94.2)	30 (5.8)	0.79 (0.55, 1.13)	0.201	0.79 (0.54, 1.17)	0.235
12-month follow-up (2025/06)	464 (89.6)	54 (10.4)	1.89 (1.25, 2.86)	0.003	1.76 (1.15, 2.69)	0.009

Note: The study design consisted of a baseline visit followed by visits at 6-month intervals. "6-month follow-up" refers to data collected in December 2024, and "12-month follow-up" refers to data collected in June 2025. The columns "Recent PrEP Use: No and Yes" represent the pooled number of observations (person-visits) across three study visits, consistent with the GEE analysis structure. The percentages represent the proportion of observations within each category (row percentages). Variables included in the multivariate model were: marital status, venues for seeking sexual partners, HIV infection risk perception, perceived PrEP effectiveness, number of HIV testing in the past six months, ever PEP use, and study visit, whose *P*-values were ≤0.2 in the univariate analyses. *P*-values ≤0.05 were considered statistically significant and are shown in bold.

Abbreviation: GEE=generalized estimating equation; PrEP=pre-exposure prophylaxis; PEP=post-exposure prophylaxis; CAI=condomless anal intercourse; STIs=sexually transmitted infections; OR=odds ratio; aOR=adjusted odds ratio; CI=confidence interval; CNY=Chinese Yuan.

The most urgent finding for public health practice is the "online paradox". Digital platforms that facilitate sexual networking for the majority of MSM appear to fail as conduits for biomedical prevention. In China, online platforms have become the dominant venue for partner-seeking, representing both opportunities and challenges for HIV prevention. Digital spaces are vast but fragmented and often lack structured health promotion. While offline venues, such as bars and community events, facilitate peer outreach and CBOs-led interventions, online users may remain disconnected from prevention services (10). To bridge this gap, it is necessary to fully leverage the communication advantages of digital channels. Based on existing HIV testing service functions, additional popular PrEP science columns, user guides, and consultation portals should be set up to develop online platforms as important carriers for PrEP publicity and service connections.

This study had four main limitations. First, the use of snowball sampling may limit the generalizability of our findings to the broader MSM population in Qingdao. Second, the primary outcome, any PrEP use in the past six months, is a broad measure of engagement and does not quantify adherence, which is the ultimate determinant of efficacy. Therefore, the 10.4% recent use rate should be interpreted as a

measure of engagement rather than as full protective coverage. Additionally, measures such as perceived PrEP effectiveness were limited to binary scales, precluding a detailed understanding of the specific reasons driving these perceptions, which warrants further qualitative investigation. Finally, although we used a prospective study design, the analysis of associations remained cross-sectional, precluding a definitive causal inference.

Sustained efforts are required to integrate PrEP into combination prevention strategies to achieve the national goal of ending the HIV epidemic. Based on these findings, public health strategies in China should prioritize strengthening health education, institutionalizing the PEP-to-PrEP bridge, and developing targeted digital interventions to close the gap between online social networking and access to biomedical prevention.

Conflicts of interest: No conflicts of interest.

Ethical statements: Approved by the Ethics Committee of the National Center for AIDS/STD Control and Prevention and the Chinese Center for Disease Control and Prevention (Approval No. X151113388, dated June 18, 2024), and conformed to the ethical principles of the Declaration of Helsinki (2024). Written informed consent was obtained from all participants before enrollment in the study.

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Corresponding author: Dongmin Li, lidongmin@chinaaids.cn.

¹ National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine, Beijing, China; ² Shandong Center for Disease Control and Prevention, Jinan City, Shandong Province, China; ³ Qingdao Center for Disease Control and Prevention, Qingdao City, Shandong Province, China.

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Outbreak Reports

Imported Cases of Monkeypox Virus Clade I a — China, 2025

Danlei Liu¹; Ye Lu¹; Chunli Hu¹; Shiwei Yu¹; Liming Xue¹; Guannan Zhang¹; Zaijiong Yi¹; Mao Mao¹; Shenwei Li¹; Qiang Wang¹; Zilong Zhang^{1,2,#}; Zhengan Tian^{1,#}

Summary**What is already known about this topic?**

Monkeypox virus (MPXV) is an orthopoxvirus comprising two major genetic clades: clade I (subclades I a and I b) and clade II (subclades II a and II b). The 2022–2023 global outbreak was predominantly driven by clade II b. Clade I viruses remain endemic in Central Africa, particularly Democratic Republic of the Congo (DRC), and are historically associated with higher virulence and fatality rates.

What is added by this report?

Two imported MPXV cases were detected in Shanghai via real-time polymerase chain reaction (PCR) in 2025, both originating from DRC. Clade-specific PCR and whole-genome sequencing identified clade I a.

What are the implications for public health practice?

These cases underscore the ongoing risk of MPXV importation through international travel. The successful detection and management of these clade I a infections demonstrate the critical importance of port entry screening, enhanced surveillance systems, and coordinated multi-agency prevention and control strategies.

Results: Both cases tested positive for MPXV infection. Clade-specific PCR and whole-genome sequencing confirmed infection with MPXV clade I a. The first case yielded partial viral genome data (approximately 7.2 kb; 3.64% genome coverage), whereas the second case produced near-complete genome sequences (196.7 kb; >99% coverage) through combined second- and third-generation sequencing platforms. Phylogenetic analysis revealed that these sequences clustered closely with clade I a strains currently circulating in the DRC.

Conclusions: These findings demonstrate the effectiveness of port-based infectious disease surveillance and multi-agency joint prevention and control mechanisms in identifying and managing imported MPXV cases. Enhanced surveillance capacity, rapid laboratory confirmation, and robust multi-agency collaboration are essential for preventing cross-border transmission of emerging infectious diseases.

ABSTRACT

Introduction: Monkeypox virus (MPXV), an emerging zoonotic pathogen, comprises two main clades with distinct epidemiological and clinical characteristics. This study reports the epidemiological investigation and genomic characterization of imported MPXV clade I a cases detected in China during 2025.

Methods: During March and April 2025, two travelers arriving at Shanghai Pudong International Airport from the Democratic Republic of the Congo (DRC) underwent screening for MPXV infection. Clinical specimens were analyzed using real-time polymerase chain reaction (PCR), clade-specific PCR, and whole-genome sequencing to characterize the viral genomes.

Monkeypox virus (MPXV), a zoonotic pathogen belonging to the genus *Orthopoxvirus*, has emerged as a significant global public health threat following its unprecedented multi-country outbreak (1). Genetically, MPXV comprises two major clades: clade I (Central African clade), encompassing subclades Ia and Ib, and clade II (West African clade), comprising subclades II a and II b (2). The 2022–2023 global outbreak, driven predominantly by clade II b, disseminated to over 100 countries and prompted the World Health Organization (WHO) to declare a Public Health Emergency of International Concern (PHEIC) (3).

Prior to 2024, all confirmed MPXV cases in China were attributed to clade II b, consistent with the global transmission pattern of the 2022 outbreak (4–5). In late 2024, China reported its first clade Ib outbreak event, originating from the Democratic Republic of the Congo (DRC), which underscored the potential for introduction of clade I viruses from endemic regions (6). Given the increasing volume of international travel between China and African

countries, the risk of importing clade I strains (including I a) has become increasingly significant.

Herein, we report two imported cases of MPXV clade I a detected in travelers returning from the DRC in 2025. This report characterizes the epidemiological features, laboratory findings, and genomic profiles of these cases, with the primary objective of demonstrating the critical role of port health surveillance and multi-agency joint prevention and control mechanisms in enabling timely detection and response to imported emerging infectious diseases.

INVESTIGATION AND RESULTS

Epidemiological Investigation

Case 1: A 33-year-old Chinese male arrived at Shanghai Pudong International Airport on March 28, 2025, aboard Flight ET684 from Addis Ababa, Ethiopia, after departing from Kinshasa, DRC. Upon arrival, he wore a mask and presented without fever or other apparent symptoms. The patient reported employment as a security guard in Africa, where his duties involved direct contact with multiple animal species, including vipers, baboons, caracals, raptors, pangolins, and crocodiles. He denied human immunodeficiency virus (HIV) infection, sexual contact with men, or exposure to known or suspected MPXV cases.

Case 2: A 39-year-old Chinese male arrived at Shanghai Pudong International Airport on April 13, 2025, aboard Flight ET684 from Addis Ababa after departing from Kinshasa, DRC. Upon arrival, he presented with papular rash-like lesions distributed across the face, arms, fingers, and chest, accompanied by dry cough and sore throat. Epidemiological investigation identified him as a close contact and workplace colleague of Case 1, whose MPXV clade I a infection had been laboratory-confirmed by Shandong CDC on March 31, 2025 (7).

Laboratory Testing

Clinical specimens, including throat swabs, vesicular fluid, whole blood, and serum samples, were collected from both cases and tested for MPXV using quantitative PCR detection kits (DaanGene Co., Ltd. and BioGerm Co., Ltd.). In Case 1, MPXV DNA was detected in serum (cycle threshold [Ct] values: 36, 34) and whole blood (Ct values: 38, 35), whereas the throat swab, which was the sole specimen type subjected to testing at the time of entry, tested negative. In Case 2, MPXV DNA was detected in vesicular fluid samples (vesicular fluid 1: Ct values 22,

20; vesicular fluid 2: Ct values 33, 36) and throat swab samples (Ct values 30, 30), while whole blood and serum samples tested negative. Subsequent clade-specific PCR assays performed on Case 2 specimens identified MPXV clade I a in vesicular fluid (Ct values: 22 and 33) and throat swab (Ct value: 31) samples; whole blood and serum samples remained negative.

Whole-genome sequencing of MPXV was performed using a multiplex PCR amplification strategy combined with high-throughput sequencing (8). Viral nucleic acids extracted from clinical specimens were amplified using multiplex PCR targeting overlapping genomic regions spanning the entire MPXV genome (approximately 197 kb). The resulting amplicons were prepared for sequencing using two distinct platforms: Illumina (second-generation sequencing) and QITAN-Gene (third-generation sequencing). Genome assembly quality was evaluated based on coverage depth (mean sequencing depth) and genome completeness (percentage of the reference genome covered). Clade assignment and phylogenetic analysis were conducted using the Nextclade platform. For Case 1, Illumina sequencing produced a partial MPXV genome of approximately 7.2 kb, representing 3.64% of the 197 kb reference genome, with a mean sequencing depth of 1,533×. For Case 2, Illumina sequencing yielded a near-complete MPXV genome of 196.6 kb (99.6% coverage, mean depth about 18,320×), while QITAN-Gene sequencing independently generated a 196.6 kb genome (99.6% coverage, approximately 3,885× depth).

Phylogenetic analysis was performed using Nextclade (<https://clades.nextstrain.org>). The resulting maximum-likelihood tree positioned the Case 2 sequence in close proximity to recent clade I a strains circulating in the DRC, clearly distinguishing it from clade II b strains that have dominated global outbreaks since 2022 (Figure 1A). The high-quality near-complete genome from Case 2 shared 99.8% nucleotide identity with an MPXV clade I a isolate from the DRC (DRC/PP_0012WRG/2024-09-10) (Figure 1B), while demonstrating 96.2% similarity to a clade I b sequence associated with the concurrent outbreak in Kinshasa, DRC (DRC/PP_004B9Y2.1/2025-04-05).

PUBLIC HEALTH RESPONSE

Shanghai Port maintained rigorous health

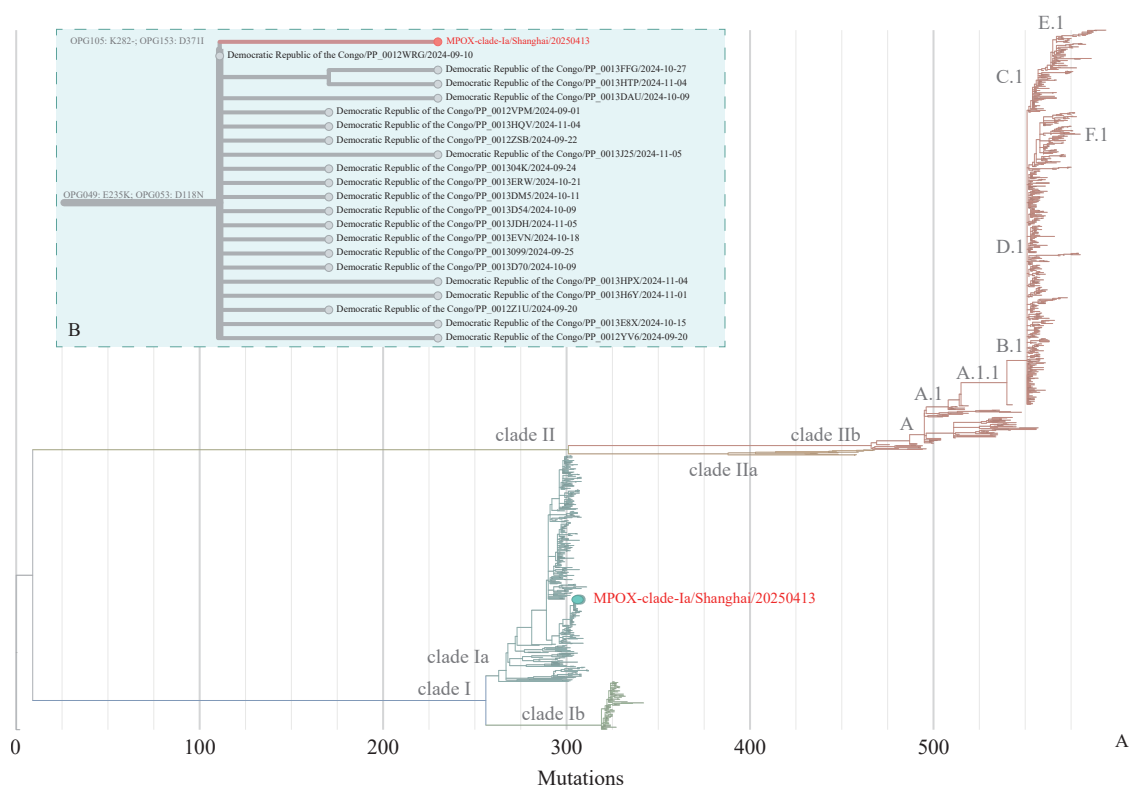


FIGURE 1. Maximum-likelihood phylogenetic tree generated using Nextclade.

Note: The viral sequences from Case 2 (highlighted in red) cluster within clade I (Central African clade) and exhibit closest genetic similarity to an MPXV strain isolated in the DRC (PP_0012WRG, GenBank accession: OZ254474, collection date: September 10, 2024).

Abbreviation: MPXV=monkeypox virus; DRC=Democratic Republic of the Congo.

surveillance protocols for arriving international travelers, encompassing temperature monitoring, symptom assessment, and detailed epidemiological interviews. Although Case 1 presented with normal body temperature and declared no symptoms upon arrival, the individual subsequently sought medical care in Shandong Province, where MPXV infection was laboratory-confirmed by Shandong CDC (7). Following notification from Shandong CDC, Shanghai Customs immediately initiated comprehensive contact tracing, identifying and monitoring all passengers seated within three rows of the confirmed case during the inbound flight. All identified close contacts underwent specimen collection and medical observation according to established protocols.

Case 2 was detected during routine entry screening when port health officers observed characteristic skin lesions. Subsequent epidemiological investigation established the epidemiological link to Case 1. Upon laboratory confirmation of both cases, Shanghai Customs promptly notified the Shanghai Municipal Health Commission and Shanghai CDC, triggering a coordinated multi-agency response. A comprehensive joint risk assessment was conducted to evaluate

potential community transmission risks, laboratory diagnostic capacity, and emergency response preparedness.

In response to these imported cases, Shanghai Port enhanced surveillance measures for travelers arriving from high-risk countries, intensified epidemiological screening of returning residents with potential exposure histories, and strengthened quarantine inspection procedures. Medical patrols and targeted health education campaigns were implemented for high-risk flights. All suspected cases underwent immediate specimen collection and laboratory testing, establishing a robust frontline defense system against cross-border pathogen introduction.

DISCUSSION

MPXV, an emerging zoonotic orthopoxvirus, has attracted sustained global attention as outbreaks have occurred in both endemic and non-endemic regions. Historically confined to Central and West Africa, MPXV infections are now increasingly detected among international travelers, underscoring the persistent risk

of cross-border transmission in an era of global mobility (1). This report documents two imported MPXV clade I a infections detected in China, representing a Central African lineage historically associated with higher virulence and elevated case fatality rates (2,9). These findings reinforce the critical need for sustained vigilance at international points of entry to intercept pathogens originating from endemic regions.

Given the increasing volume of international travel between China and MPXV-endemic regions, maintaining and strengthening port health surveillance remains essential (9). The primary public health significance of these cases extends beyond the rarity of the viral lineage to demonstrate the effectiveness of coordinated multi-agency response systems (10). Through collaboration among customs authorities, health commissions, and CDCs, this integrated approach plays a pivotal role in coordinating resources, ensuring rapid response, and achieving closed-loop management of cases and their contacts.

Laboratory assays of these cases showed that pathogen-detectable sample types vary depending on the infection stage and further underscored the critical importance of integrated laboratory capacity and genomic characterization within port health surveillance systems. The application of clade-specific PCR and whole-genome sequencing enabled precise lineage identification and comprehensive risk assessment, directly supporting evidence-based decision-making for public health interventions. Notably, genomic analysis provided essential context for distinguishing imported high-virulence lineages from strains associated with ongoing global outbreaks, thereby enhancing situational awareness and improving response precision.

In conclusion, these imported MPXV clade I a cases provide compelling evidence that well-functioning port health quarantine systems, supported by robust laboratory and genomic surveillance coupled with multi-agency coordination, effectively mitigate the risk of cross-border transmission of emerging infectious diseases. Continued investment in port biosecurity infrastructure and diagnostic capacity will be essential for safeguarding public health security. Such investments are particularly critical amid increasing global population mobility and the ongoing threat of pathogen importation from endemic regions.

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Corresponding authors: Zilong Zhang, zhangzilong@customs.gov.cn; Zhengnan Tian, tianzhengan@customs.gov.cn.

¹ Shanghai International Travel Healthcare Center, Shanghai Customs District, Shanghai, China; ² Center for Global Health, School of Public Health, Nanjing Medical University, Nanjing City, Jiangsu Province, China.

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