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ORIGINAL RESEARCH

Health Economics Evaluation of Bictegravir/Emtricitabine/Tenofovir for a First-Line Treatment of HIV-1 Infection in China

Wenjuan Wang[1,*], Dachuang Zhou[1,*], Kejia Zhou[1], Di Zhang[1], Hao Li[1], Hongliu Zhang[1], Xin Jiang[1], Ruihua Wang[1], Xi Wang[2], Wenxi Tang[1]

[1]Center for Pharmacoeconomics and Outcomes Research, China Pharmaceutical University, Nanjing, Jiangsu Province, 211198, People's Republic of China; [2]Infection Center, Beijing You'an Hospital, Capital Medical University, Beijing, 100069, People's Republic of China

*These authors contributed equally to this work

Correspondence: Wenxi Tang; Xi Wang, Email tokammy@cpu.edu.cn; wangxi35@ccmu.edu.cn

Purpose: This study aims to evaluate the economic value of Bictegravir/emtricitabine/tenofovir (B/F/TAF) as a first-line treatment for HIV-1 infection in China, where such evaluations are currently lacking.

Patients and Methods: We developed a monthly-cycle Markov model to evaluate the economics of B/F/TAF versus dolutegravir/lamivudine (DTG/3TC) as a first-line ART for adult HIV-1 patients over a lifelong time. The social costs, quality-adjusted life years (QALYs), incremental net monetary benefit (INMB), and incremental cost-effectiveness ratio (ICER) have been analyzed using health economic methods. Sensitivity analyses were conducted for the result validation. Taking into account the transmissibility of HIV, we have developed a scenario within a dynamic model across the entire population in China, to conduct a health economic evaluation of the two drugs over 30 years. Model precision was tested using relative standard deviation (RSD).

Results: In the Markov model, B/F/TAF had higher per-person costs compared to DTG/3TC ($44,381.33 vs $42,160.13), but also resulted in greater QALYs (11.6771 vs 11.5389), leading to a per-person INMB of $3072.26 (WTP = 3GDP) and an ICER of $16,052.42 per QALY. Uncertainty analyses confirmed the robustness of these results. The dynamic model further indicated that B/F/TAF was both cost-benefit and cost-effective, with a per-person INMB of $7.33 (WTP = 3GDP) and an ICER of $7,953.72 per QALY, although it exhibited a higher RSD.

Conclusion: After adopting the B/F/TAF regimen in China, the cost-benefit and cost-effectiveness of HIV prevention and treatment have significantly improved. We should advocate for B/F/TAF as the first-line treatment to enhance HIV management.

Keywords: HIV, Markov, dynamic model, bictegravir/emtricitabine/tenofovir, China

Introduction

The gravity of the HIV epidemic in China persisted unabated until 2020, with a reported 1.05 million individuals (prevalence: 0.08%) afflicted by HIV, as disclosed by *National Center for AIDS/STD Control and Prevention*.[1] The advent of ART substantially curtailed the HIV-related mortality rate, aligning it closely with that of common chronic ailments.[1] The financial commitment from the Chinese government for HIV/AIDS antiviral treatment grew from $24 million in 2004 to $550 million in 2020.[2] This emphasizes the urgent need to carefully choose antiretroviral drugs that are both effective and economical to strengthen the overall management of HIV.

Guidelines from esteemed entities such as World Health Organization (WHO), Chinese Guidelines for Diagnosis and Treatment HIV/AIDS (2021), and US Department of Health and Human Services (DHHS) all uniformly recommend a regimen comprising two nucleoside reverse transcriptase inhibitors (NRTIs) and a non-NRTI drug (core agent) for a first-line treatment.[3–5] Among the core agents selected by ART, integrase inhibitors (INSTIs) are optimized in terms of high efficiency, low toxicity, and drug resistance compared with the previous non-nucleoside reverse transcriptase

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inhibitors (NNRTIs) and protease inhibitors (PIs).[6] In China, four INSTIs—raltegravir (RAL), Elvitegravir (EVG), DTG, and BIC—are currently enlisted, with RAL and EVG being first-generation, and DTG and BIC classified as second-generation. Bictegravir (BIC), an INSTI presented solely in the form of a fixed-dose compound (B/F/TAF), includes the other components Emtricitabine (FTC) and Tenofovir Alafenamide (TAF). B/F/TAF has emerged as the first-line favored primary treatment for HIV in numerous nations owing to its commendable viral inhibition rate, safety profile, and resistance characteristics.[3–5,7] BIC is particularly noteworthy for its enhanced antiviral efficacy against non-B subtypes of HIV-1, outperforming both RAL and EVG in this regard. Despite the similar in vitro inhibitory potency of BIC and DTG, BIC demonstrates structural robustness, leading to sustained effectiveness and decreased vulnerability to drug interactions.[7] Clinical trials have proved that B/F/TAF's efficacy in the initial treatment of HIV-1 is on par with the prevailing DTG-based ART regimen, with superior safety and resistance profiles and an enhanced patient medication experience.[8,9] DTG/3TC is the only fixed-dose compound containing DTG among the first-line preferred options in the Chinese guidelines.[3]

Compared with DTG/3TC, the more expensive B/F/TAF exhibits superior clinical performance. However, the value of the additional health benefits provided by B/F/TAF, relative to its higher cost than DTG/3TC, remains to be determined. In international studies, Markov models can simulate inevitable multi-line treatments in lifelong ART, along with the occurrence of clinical events such as tumors or opportunistic infections.[10–12] In China, economic evaluations of ART are relatively limited, with exploration being rather superficial. For instance, Yogesh's (2019) study focused on a short-term five-year horizon,[13] and Min Li's (2023) lifelong simulation considered clinical events but still did not account for multi-line treatments.[14] Based on international research, Markov models could be more maturely employed for the economic assessment of ART in China. However, ART's function of reducing transmission risks[15] surpasses the simulation capability of Markov models, highlighting the need for a dynamic model. Currently, dynamic models for the economic evaluation of HIV interventions focus on preventive measures, such as screening and risk behavior interventions, but none have been developed for evaluating ART.[16–18] This study aims to conduct a health economic analysis of B/F/TAF compared with DTG/3TC as first-line therapy for HIV-1, incorporating a scenario that accounts for HIV transmission to provide a more comprehensive analysis.

Materials and Methods

This study conducted a cost-effectiveness analysis comparing two first-line HIV treatment strategies—B/F/TAF and DTG/3TC—from a societal perspective in China. The primary outcomes included total costs, Quality-Adjusted Life Years (QALYs), incremental net monetary benefit (INMB), and the Incremental Cost-Effectiveness Ratio (ICER). The willingness-to-pay threshold was set at 1–3 times China's 2022 per capita GDP ($12,741.11).[19]

Model Design

Model Structure and Assumptions

A Markov decision-analytic model, developed in Microsoft Excel 2019, simulated HIV disease progression over an 80-year lifespan using monthly cycles aligned with drug regimens.[11] Patients in the B/F/TAF group started with B/F/TAF as the preferred first-line treatment, transitioning to an alternative DTG/3TC group if virus suppression is not achieved. Similarly, those in the DTG/3TC group began with DTG/3TC, opting for an alternative B/F/TAF regimen.[11] The decision tree model structure was illustrated in Figure 1a. Following China's HIV clinical guidelines,[3] patients failing first-line treatment were switched sequentially to standardized second-line (LPV-based), which has been the historical standard since 2009,[20] and third-line (DRV-based) regimens.

Model Stages and Transitions

The model consisted of five health stages based on CD4 cell counts (stage 5: more than 500 cells/mm^3, stage 4: 350–500 cells/mm^3, stage 3: 350–200 cells/mm^3, stage 2: 100–200 cells/mm^3, and stage 1: less than 100 cells/mm^3), which were derived from the immunological classification of HIV/AIDS by WHO and published literature.[11,21] Further classification included the first-line treatment, discontinuation in the first-line treatment, the second-line treatment, discontinuation in the second-line treatment, the third-line treatment, and discontinuation in the third-line treatment. HIV-1 patients were

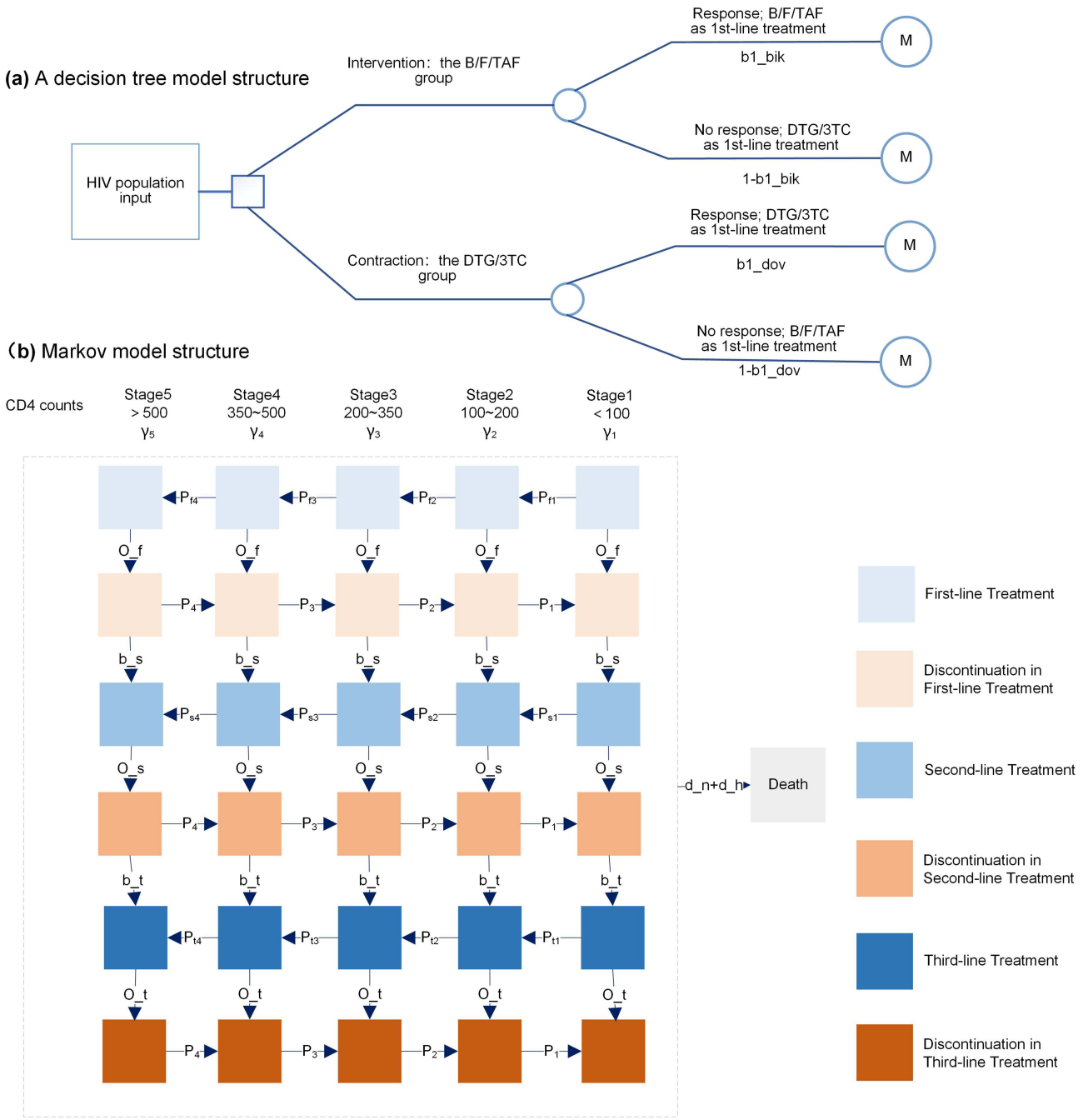

Figure 1 Model Structure: (**a**) the decision tree model Structure and (**b**) the Markov model Structure.
Abbreviations: CD4, CD4-positive T-lymphocytes, immune cells; ART, antiretroviral therapy; γ1~γ5, the proportion of patients newly diagnosed in each stage; d_n, the age-varying natural mortality; d_h, the HIV-related mortality; b1_bik, the viral suppression rate of B/FTAF in the first-line treatment; b1_dov, the viral suppression rate of DTG/3TC in the first-line treatment; b_s, the viral suppression rate of the ART in the second-line treatment; b_t, the viral suppression rate of the ART in the third-line treatment; O_f, the discontinuation rate of the ART in the first-line treatment; O_s, the discontinuation rate of the ART in the second-line treatment; O_t, the discontinuation rate of the ART in the third-line treatment; P1~P4, the transition probability between stages in the absence of treatment; Pij (i∈{f,s,t},j∈{1,2,3,4}), the transition probability between stages under the first/second/third-line treatment.

subsequently divided into 30 states, as illustrated in Figure 1b. Moving to an adjacent stage or remaining in the same stage within one cycle depended on whether drug discontinuation occurred and changed CD4 counts. For patients maintaining treatment, CD4 counts could increase, potentially advancing to a higher CD4 stage. However, for those discontinuing treatment or failing virologic suppression, CD4 counts could decrease, potentially regressing to a lower CD4 stage.

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Model Validation

The model's structure and assumptions were rigorously reviewed by clinical experts to ensure their validity, and the model was further validated through comprehensive sensitivity analyses, as detailed in Sensitivity Analyses, to ensure robust outcomes.

Model Parameters

Cohort Characteristics

We established a cohort model of 100,000 adult HIV patients (≥18 years old) based on two key considerations: (1) BIC/F/TAF and DTG/3TC are only approved for adult use; and (2) Chinese national data (2011–2019) showed adults accounted for 96% of new HIV cases.[22] The cohort was stratified into five disease stages (25%, 25%, 25%, 12.5%, 12.5% distribution) based on established CD4 count thresholds (500, 350, and 200 cells/μL), consistent with findings from Chinese clinical studies.[23–26]

Clinical Parameters

ART efficacy was measured by viral suppression rate (<50 copies/mL) and immune response (average CD4 increase). These efficacy parameters for B/F/TAF were derived from the GS-US-380-1489 trial,[8,27] and for DTG/TAF, it originated from the GEMINI-1 (NCT02831673) and GEMINI-2 (NCT02831764) trials,[28,29] with data reported for both 0–48 weeks and 48–96 weeks. To facilitate the implementation of this study, efficacy parameters for second-line or third-line treatments were only reported for the 0–96 weeks. The pertinent data are meticulously presented in Table 1. A subtle transition in CD4 count was anticipated after the early ART-driven CD4 rise.[11] Consequently, it was assumed that CD4 count remained unchanged after 96 weeks of all ART regimens. The data in Supplementary Table S1 present all transition probabilities between adjacent stages, based on changes in CD4 cell counts resulting from ART drug intervention. Supplementary Material 1 provides the methodology for calculating these probabilities.

Discontinuation of ART was classified as virological (drug resistance) and non-virological (mainly adverse reactions) reasons. The discontinuation rates for each ART regimen were derived from relevant literature, including trial data,[8,11,12,27–31] with specific details presented in Table 1. During the period of discontinuation, the CD4 cell counts of HIV patients decreased by 4.3 cells/mm^3 each month.[32]

Mortality included age-varying natural mortality and HIV-related mortality. These data on age-varying natural mortality were sourced from GBD in 2021 and detailed in Supplementary Table S2.[51] HIV patients with lower CD4 count levels faced higher mortality rates. These data were obtained or calculated based on the literature and are presented in detail in Table 1.[33–35]

Additional clinical events comprised AIDS-defining events (ADEs) and adverse reactions (AEs) associated with various ART regimens, incurring disutility and cost. Specifically, there are 27 types of ADEs, including inflammation, infection, tumors, and cancers. Diverse statuses correlated with distinct rates of ADEs.[36–38] Most ART drugs manifested

Table 1 Clinical Parameters, Costs, and Utility

The Therapeutic Effect of ART			
ART regime	**Period**	**Viral suppression rate (±5%, beta)**	**Monthly change in CD4 cells, cells/mm^3 (±10%, gamma)**
B/F/TAF[8,27]	Week 0 to 48	92.40%	19.42
	Week 48 to 96	88.00%	4.50
DTG/3TC[28,29]	Week 0 to 48	91.50%	18.68
	Week 48 to 96	86.00%	3.74
Second line[30]	Week 0 to 96	85.75%	8.83
Third line[31]	Week 0 to 96	86.00%	8.38
Any ART regime[11]	Week after 96	/	0

(*Continued*)

Table 1 (Continued).

Drug discontinuation (monthly)[8,11,12,27–31]		
ART regime	**Virological discontinuation (±5%, beta)**	**No-virological discontinuation (±5%, beta)**
B/F/TAF	0.4058%	0.4900%
DTG/3TC	0.5053%	0.5050%
Second line	0.6385%	0.8400%
Third line	0.6265%	0.3200%
Change in CD4 cells (drug discontinuation), count/μL[32] (±10%, gamma)		−4.3

HIV related mortality rate (monthly)[33–35] (±5%, beta)				
Stage 5	Stage 4	Stage 3	Stage 2	Stage 1
0.0250%	0.3274%	0.4868%	1.4600%	2.9000%

The rates of other clinical events (monthly) (±10%, gamma)			
	ADEs[36–38]	**ART regime**	**AEs**[11,39–41]
Stage 5	0.0600%	B/F/TAF	1.9400%
Stage 4	0.3400%	DTG/3TC	1.3900%
Stage 3	0.8800%	Second line	2.0775%
Stage 2	3.0000%	Third line	4.0000%
Stage 1	3.4000%		

Cost($/month) (±10%, gamma)		
Direct medical cost		
	Cost of medicines[42]	**Cost of AEs**[8,29,39,43–46]
B/F/TAF	169.58	17.98
DTG/3TC	133.40	11.64
Second line	43.55	44.44
Third line	363.33	24.66
HIV test[47]	22.30	
CD4 test[47]	6.93	
ADEs[37,43,48]	7272.00	

Direct non-medical cost: transportation cost[49]					
	Stage 5	**Stage 4**	**Stage 3**	**Stage 2**	**Stage 1**
Patients (outpatient)	4.71	4.71	4.71	8.39	8.39
Patients (inpatient)	0.10	0.10	0.10	0.13	0.13
Relatives (outpatient)	0.74	0.74	0.74	0.91	0.91
Relatives (inpatient)	3.33	3.33	3.33	6.54	6.54
Indirect cost[13]	0	53.88	36.09	209.94	209.94
Utility (±5%, beta)					
	Stage 5	Stage 4	Stage 3	Stage 2	Stage 1
Healthy stages[13]	0.899	0.899	0.8860	0.8610	0.8325
AEs[50]	−0.0120				
ADEs[37,43,48]	−0.1609				

Notes: Stage 5 (CD4 cell counts ≥ 500 cells /mm^3), stage 4 (350–500 cells / mm^3), stage 3 (350–200 cells / mm^3), stage 2 (100–200 cells / mm^3), stage 1 (less than 100 cells / mm^3). ±5% is a range floating setting for smaller parameters (≤1), based on beta distribution; and ±10% is a range floating setting for larger parameters, based on gamma distribution.

Abbreviations: ART, Antiretroviral Therapy; ADEs, AIDS-defining events; AEs, adverse reactions.

a diverse array of AEs, including anemia, nausea, gastrointestinal effects, and others. The incidence of adverse reactions for each ART regimen in this study was derived from relevant trials and other literature, as shown in Table 1.[11,39–41]

Costs

As this study adopted a societal perspective, costs were incorporated into direct medical costs, direct non-medical costs, and indirect costs. All costs inflated to 2022 values and are calculated based on the average exchange rate in 2022 (1 USD = 6.7261 RMB).[19]

Direct medical costs were considered in the following: (1) expenditures on ART regimens, (2) examination costs, (3) costs associated with adverse reactions to ART regimens, and (4) administrative expenses for ADEs. Medicine prices were sourced from *China Pharmaceutical Information Database*.[42] The second-line cost included the prices of the individual components LPV/r, TDF (tenofovir disoproxil fumarate), and 3TC (lamivudine). The third-line cost comprised the prices of the combination DRV/r, DTG, TDF, and 3TC. Examination costs, involving both HIV and CD4 cell examinations, were derived from official prices provided by Jiangsu Province (in China).[47] Costs related to ADEs and AEs treatment were meticulously calculated based on the likelihood of clinical manifestation. The weighted average cost per month for each occurrence of ADEs, considering the proportional representation and individual cost of each ADE type, was determined to be $7272.00.[37,43,48] Additionally, the monthly costs per occurrence of AEs for each ART regimen were computed following a similar methodology.[8,29,39,43–46] The detailed classification and costs of ADEs and AEs were conveniently presented in Table 1, with further elaboration available in Supplementary Tables S3 and S4. The direct non-medical expenses comprised four categories, taking into account transportation costs for patients and their relatives traveling to outpatient or inpatient clinics. These costs were gleaned from an empirical study that involved patient questionnaires and expert interviews.[49] Furthermore, indirect costs were considered productivity losses and associated expenses using relevant Chinese data.[13]

Utilities

HIV patients exhibited varying utility levels across different health stages based on CD4 count,[13] with the utility decreasing as the CD4 count declined. The occurrence of AEs[50] and ADEs would reduce utility.[37,43,48] These data were shown in Table 1.

Discount Rate

Both costs and outcomes were discounted annually at a rate of 5%, by *China Guidelines for Pharmacoeconomic Evaluation*.[52]

Sensitivity Analyses

To evaluate the robustness of the model results, comprehensive sensitivity analyses were conducted using three complementary approaches. First, one-way sensitivity analyses (OWSA) were performed by systematically varying each parameter within ±5% or ±10% of baseline values while holding other parameters constant, enabling identification of the most influential parameters. Second, probabilistic sensitivity analysis (PSA) was implemented using 10,000 Monte Carlo simulations, with clinical probabilities following beta distributions and costs following gamma distributions, generating posterior distributions of incremental costs, QALYs, and cost-effectiveness outcomes. This approach allowed construction of cost-effectiveness acceptability curves to determine the probability of B/F/TAF being cost-effective across various willingness-to-pay thresholds. Additionally, the impact of mortality assumptions was evaluated by testing three scenarios: baseline 2021 rates, and projected 2050 and 2100 rates. Together, these analyses provided a rigorous assessment of parameter uncertainty and strengthened confidence in the model conclusions.

Scenario Analysis - Considering HIV Transmission

Model Design

To address the limitations of Markov models in representing HIV transmission dynamics, we adopted a dynamic modeling approach combined with scenario analysis.

Model Structure and Assumptions

We constructed a dynamic model to simulate HIV spread among the adult population in China from 2015 to 2044, using annual cycles aligned with behavioral and clinical monitoring intervals. The study population was stratified into five mutually exclusive subgroups based on transmission risk: MSM (Men who only have sex with men); MIDU (Male Injecting drug-using men who are not MSM); FIDU (Female Injecting drug-using), Males (non-MSM or non-MIDU), Females (non-MIDU).[3] This stratification scheme was adopted due to both the unavailability of reliable data on MSM who inject drugs and the need to separately analyze these high-risk populations.

The modeling framework was adapted from the classical Susceptible-Infectious-Removed (SIR) model.[16] The SIR model considered that susceptible individuals could become infected with the virus from HIV patients, with different risks of infection among various subgroups. Specifically, it was assumed that Males (non-MSM or non-MIDU) and Females (non-MIDU) could only be infected through heterosexual intercourse, MSM through homosexual behavior, and injecting drug users through both heterosexual and bloodborne transmissions.

Model Stages and Transitions

Disease progression and state transitions between annual cycles were governed by multiple factors. The dynamic model simulating the progression of HIV disease and HIV transmission is illustrated in Figure 2. Moving to an adjacent stage or remaining in the same stage within one cycle depended not only on whether drug discontinuation occurred and changed in CD4 count but also on the impact of ART treatment on infection risk. Some HIV patients were diagnosed and received antiviral treatment, which reduced new incidence due to the decreased risk of transmission. However, in cases where HIV suppression failed due to drug discontinuation, the risk of transmission did not decrease. The detailed parameters for each state transition of these five subtypes (shown in Supplementary Table S5) and the calculation formulas are Supplementary Material 2.

Model Validation

The model was validated through two main approaches. The HIV infection data for the five subgroups predicted by the dynamic model closely matched the actual data from 2015 to 2019, with R^2 values close to 1, confirming the accuracy of

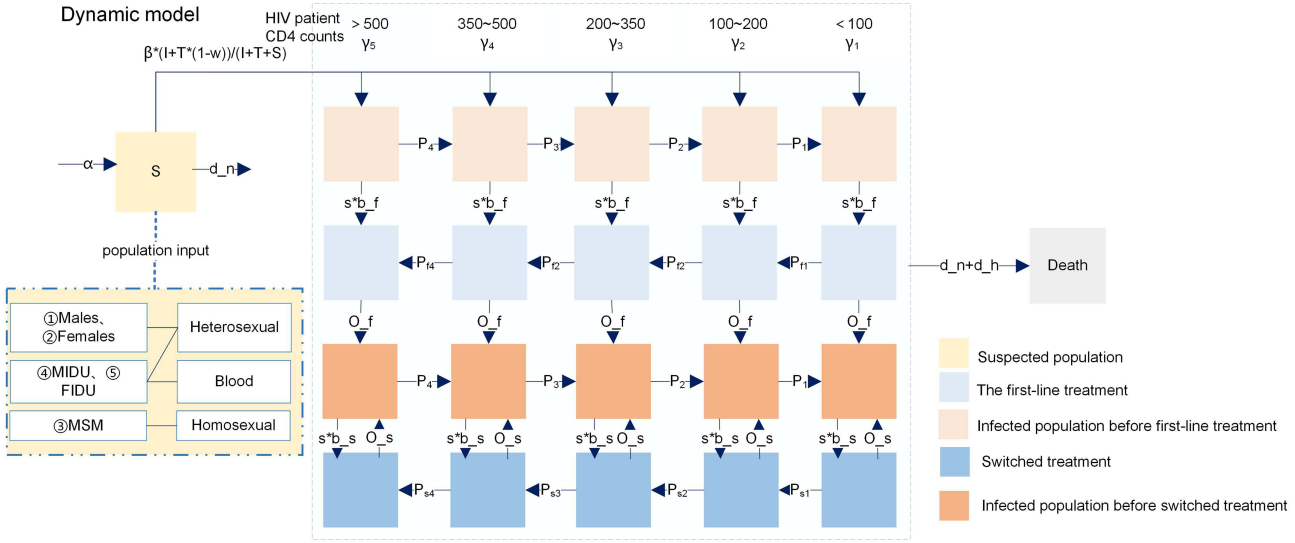

Figure 2 The dynamic model Structure.

Abbreviations: CD4, CD4-positive T-lymphocytes, immune cells; ART, antiretroviral therapy; MSM, men who have sex with men; MIDU, male injecting drug users; FIDU, female injecting drug users, male (non-MSM or MIDU), female (non-FIDU); I, the infected; T, the treated; S, the susceptible; γ1~γ5, the proportion of patients newly diagnosed in each stage; d_n, the age-varying natural mortality; d_h, the HIV-related mortality; b_f, the viral suppression rate of B/FTAF in the first-line treatment; b_s, the viral suppression rate of the ART in the switched treatment; O_f, the discontinuation rate of the ART in the first-line treatment; O_s, the discontinuation rate of the ART in the switched treatment; P1~P4, the probability without treatment; Pij (i∈{f,s},j∈{1,2,3,4}), the transition probability between stages under the first/switched-line treatment; β, the coefficient of infection (incidence/infection rate); s, the coverage rate for diagnosed and treatment; α, the natural growth rate of population; w, the probability of reduced infectivity.

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the model (Supplementary Figure S1). Secondly, the uncertainty analysis also confirmed the stability of the model, with the results presented in Scenario Analysis.

Model Parameters

Demographic and Transmission-Related Parameters

We have collated the total number of individuals and the total number of infected individuals for the five subgroups from 2015 to 2019. These data were sourced from *China Statistical Yearbook*,[53] the international homoerotic association,[54] *National Center for AIDS/STD Control and Prevention*,[22,55–61] *China Anti-Drug Network*, and other relevant sources.[56,57] The data from the year 2015, serving as the initial values, are presented in Supplementary Table S6. The infection coefficient, denoted as β, represented the ratio of the new incidence rate to the infection rate in the model. The non-linear least square method was used to fit the β of each subgroup with the data from these 5 years.

Some studies have confirmed that patients almost did not have the risk of transmission when treated with ART to control their HIV viral load to a lower level. The study set a 96% transmission risk reduction rate for patients effectively suppressing HIV.[58] This study considered the probability of examination and treatment to be 74.93%, based on data from Guangxi Province (in China) in 2021.[59]

Other Parameters

Moreover, a natural growth rate of 1.1963% was factored into this study.[53] The natural mortality rate of each subgroup was considered as follows: Males (non-MSM or non-MIDU), Females (non-MIDU) and MSM are normal populations, and the average natural mortality rate from 2015 to 2019 was 0.7068%.[53] For injecting drug users, MIDU was 7.18%, and FIDU was 5.48%.[62]

The clinical parameters, costs, utilities, and discount rate required for the dynamic model were based on the data from the decision-Markov model. Notably, the clinical parameters for switch therapy are calculated based on the average of second- and third-line clinical parameters. These data were converted to yearly units when utilized in the dynamic model.

Results

Base Case

The base-case analysis of the decision-Markov model, as detailed in Table 2, showed that, compared to the DTG/3TC group, the B/F/TAF group gained 0.1384 extra QALYs for an extra cost of $2,221.21, resulting in an INMB of $3072.26 (WTP = 3GDP) and an ICER of $16,052.42 per QALY gained per patient (1.26 times the GDP).

The cost of medications accounted for over half of the total expenditures, while costs associated with examinations, ADEs, AEs, direct non-medical costs, and indirect costs were relatively minor and showed similar proportions across the two model groups. The B/F/TAF group significantly alleviated the health burden. Compared to the DTG/3TC group, the B/F/TAF group collectively reduced the occurrences of 622 hIV-related deaths and 828 ADEs per 100000 hIV patients.

Sensitive Analyses

In OWSA, we found that the ART effect (viral inhibition rate and immune response) and cost of B/F/TAF and DTG/3TC were the parameters that most influenced the results (Figure 3a). However, the fluctuations of all outcomes from OWSA

Table 2 Discounted Costs, QALYs, INMB, and ICERs

	Total QALYs	Total Costs, USD	The Proportion of the Cost of Each Part, %					INMB, USD	ICER, USD/QALY	HIV-Related Deaths	Incidence of ADEs
			ART	Test	AEs	ADEs	Others				
B/F/TAF	11.6771	44,381.33	54.10%	25.81%	0.01%	8.87%	11.21%				
DTG/3TC	11.5387	42,160.13	51.33%	27.04%	0.01%	9.54%	11.88%				
Incremental	0.1384	2221.21	2.77%	−1.23%	0.00%	−0.67%	−0.67%	3072.26	16,052.42	−622	−828

Abbreviations: QALYs, quality-adjusted life-years; INMB, incremental net monetary benefit; ICER, incremental cost-effectiveness ratio; LY, life year.

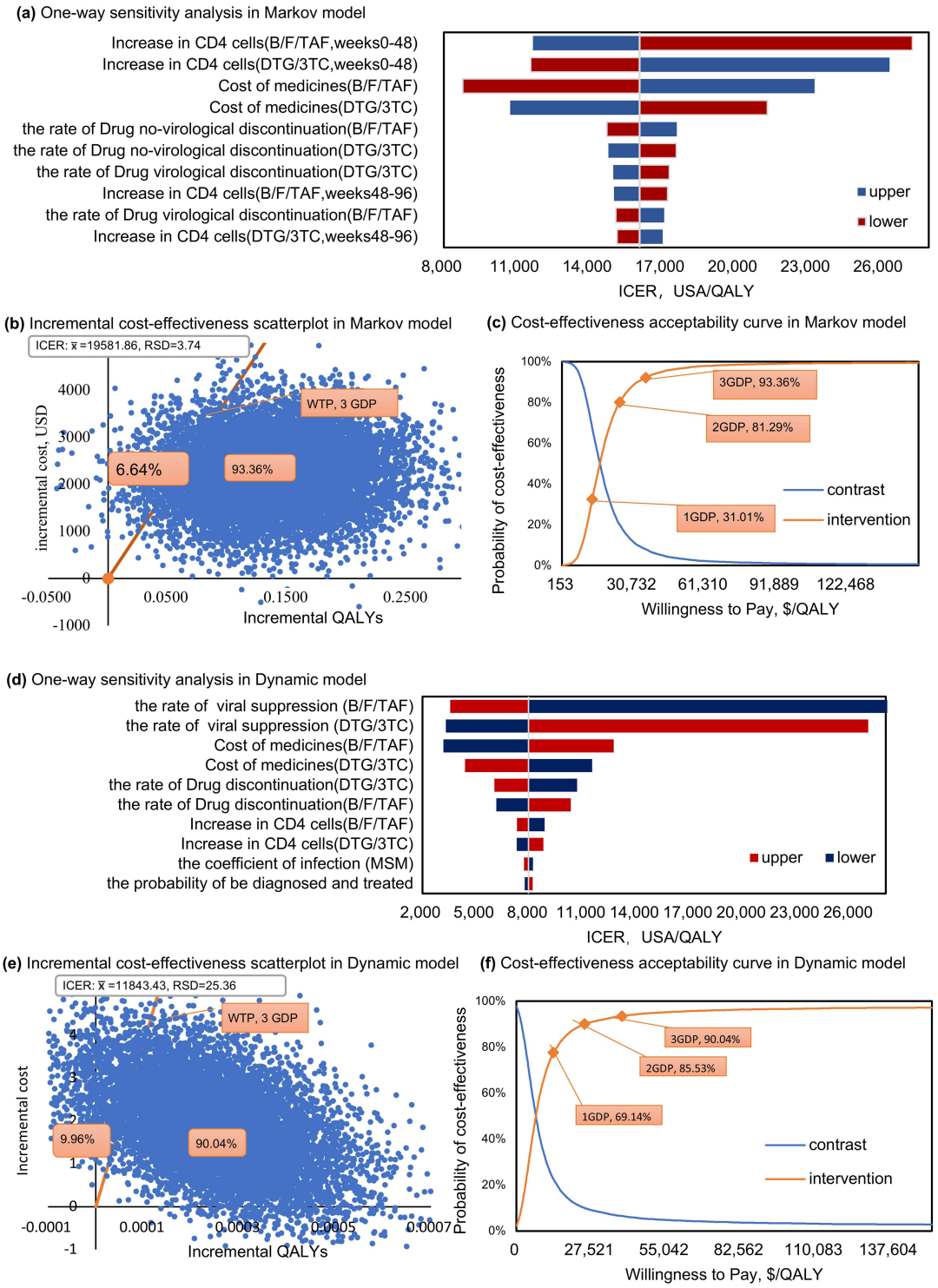

Figure 3 (**a**) One-way sensitivity analysis in the Markov model; (**b**) Incremental cost-effectiveness scatterplot in the Markov model; (**c**) Cost-effectiveness acceptability curve in the Markov model; (**d**) One-way sensitivity analysis in the dynamic model; (**e**) Incremental cost-effectiveness scatterplot in the dynamic model; (**f**) Cost-effectiveness acceptability curve in the dynamic model.

Notes: (**a** and **d**) we tested the impact of parameter changes on the results by varying each parameter by ±5% or ±10%. The "upper" and "lower" bars in the figure represent the maximum and minimum values of the results (ICER) within the range of parameter changes. (**b** and **e**) illustrate the variation of ICER under different parameter changes in the probabilistic sensitivity analysis, with each point representing the outcome of a single simulation, allowing for a visual assessment of the distribution of results. (**c** and **f**) show the probability of B/F/TAF being cost-effective compared to DTG/3TC across different willingness-to-pay (WTP) thresholds.

Abbreviations: QALYs, quality-adjusted life-years; INMB, incremental net monetary benefit; ICER, incremental cost-effectiveness ratio; WTP, willing to pay; RSD, Relative Standard Deviation.

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fell within the acceptable range WTP. PSA indicated a high degree of confidence in the results. At a willingness-to-pay threshold of 3 times the GDP, the probabilities of cost-effectiveness for B/F/TAF in the decision-Markov model were 93.36% (Figure 3b). Through the examination of the cost-effectiveness acceptability curves, it was determined that when the willingness-to-pay threshold was set at the per capita GDP, the probability of B/F/TAF being considered acceptable was 31.01% in the Markov model. If the threshold was set at double the per capita GDP, the probability reached 81.29% in the decision-Markov model (Figure 3c). The results obtained are stable, and the specific data are provided in Supplementary Table S7.

Scenario Analysis

The base-case analysis of the dynamic model showed that the B/F/TAF group was associated with a 30-year cost of $33.80 and expected QALYs of 14.9412, while the DTG/3TC group incurred a 30-year cost of $31.88 and expected QALYs of 14.9409 per Chinese adult. This led to a per-person INMB of $7.33 (WTP = 3GDP) and a per-person ICER of $7,953.73 per QALY (0.62 times the GDP) (shown Supplementary Table S8). In the dynamic model, compared to the DTG/3TC group, the B/F/TAF group reduced the occurrences of 55,547 new HIV infections (five subgroups from 2015 to 2044 are detailed in Supplementary Figure S2), 29,979 hIV-related deaths, and 70,399 ADEs.

The OWSA results fell within the acceptable WTP range (Figure 3d). At a willingness-to-pay threshold of three times the GDP, the probability of B/F/TAF being cost-effective in the dynamic model was 90.04% (Figure 3e). The calculation of 10,000 ICERs from PSA revealed RSDs (Relative Standard Deviations) of 3.74 (Figure 3c) for the Markov model and 25.36 for the dynamic model (Figure 3f). This suggests that in the simulation, the dynamic model yields relatively less stable results compared to the Markov model.

Discussion

B/F/TAF has been included as first-line HIV treatment guidelines in China, the United States, and WHO due to its outstanding clinical efficacy. However, its relatively higher cost has limited its widespread clinical application. Therefore, a pharmacoeconomic evaluation is necessary to determine if the higher medication cost leads to greater health benefits. This study aims to evaluate the cost-benefit and cost-effectiveness of B/F/TAF in comparison to DTG/3TC for treatment-native adults of HIV-1 Infection in China, utilizing Markov and dynamic models. In the decision-Markov model, B/F/TAF demonstrated an INMB of $3,808.23 and an ICER of $16,052.42 per QALY gained compared to DTG/3TC. The dynamic model further indicated that B/F/TAF was both cost-beneficial and cost-effective, with a per-person INMB of $7.33 and a per-person ICER of $7,953.73 per QALY. We attempted to analyze the reasons supporting the cost-benefit and cost-effectiveness of B/F/TAF. Firstly, B/F/TAF demonstrated higher clinical effectiveness than DTG/3TC, resulting in a reduction in ADE occurrence, HIV-related deaths, and new HIV cases. These gained extended beyond individual health improvements to encompass savings in direct non-medical and indirect costs, coupled with a decrease in the likelihood of transmission. Secondly, as HIV is a chronic infectious disease, its treatment costs are intricate, with antiretroviral drugs constituting only around 50% of the overall costs, and first-line drugs comprising merely 20%. Consequently, the price advantage of DTG/3TC lacked significant clinical and macro-application impact.

This study introduced some methodological innovations. First, it developed an optimized decision-Markov model to evaluate ART for treating HIV-1 patients in China. The decision-Markov model simulated the details of ART for treating HIV, including switching treatment plans. In clinical drug selection, patient demands took precedence, making a Markov model based on patient cohorts more aligned with actual needs. The model provided a detailed simulation of HIV-1 patients undergoing lifelong multi-line ART treatment. In terms of cost management, the model not only considered the costs of medications and testing but also factored in the costs associated with managing AEs of different ART drugs and ADEs related to CD4 changes. Additionally, it accounted for direct non-medical costs and indirect costs. Secondly, the dynamic model took into account transmission factors and assessed the preventive effects of ART, offering improved guidance for HIV prevention and control. A dynamic model, which thoroughly incorporates both treatment and transmission risk prevention, exhibits greater theoretical robustness in the economic assessment of various ART options. Regarding parameter considerations, the dynamic model must take into account not only clinical, cost, and utility parameters but also demographic parameters for five subgroups and parameters related to transmission. This also

precisely explains why the dynamic model has lower precision compared to the Markov model, resulting from diverse parameter types and more complex algorithmic processes. Researchers must weigh trade-offs between simplicity and comprehensiveness to ensure the selected model aligns with their study goals. The Markov model is ideal for simulating patient cohort treatments and cost management, but it cannot assess disease transmission. In contrast, dynamic models offer a more comprehensive theoretical framework, integrating both treatment and prevention strategies. However, they are more complex and demand extensive data. The choice depends on research objectives: for patient cohort analysis, the Markov model is suitable, while dynamic models are better for public health evaluations.

We have included international findings for comparative analysis with our results. In an economic evaluation of DTG-based regimens in Ethiopia, 15.3 QALYs per patient (≥18 years of age) over a lifetime were obtained compared to EFV-based regimens (vs 14.7 QALYs).[11] The Ethiopian study reported slightly higher results than the QALYs obtained in our Markov model, mainly due to the inclusion of disutility associated with ADEs and AEs, which was not considered in the Ethiopian study. In an economic evaluation of DTG-based treatment regimens in the United States, compared with EFV-based regimens, the cost was calculated from the perspective of the US payer: 88.20% for medicines (vs 88.42%), 8.39% for tests (vs 8.18%), and 3.41% for events (vs 3.40%).[37] The order of cost distribution in our study, from highest to lowest, was the cost of medicine, the cost of tests, and the cost of event management.

At present, HIV/AIDS treatment in China has entered the era of "Troika" optimization, ensuring the provision of low-end (free drugs), mid-end (Medicare drugs), and high-end (self-financed drugs) options for patients.[61] This setup allows individuals to select treatments aligned with their preferences. For example, economically well-off HIV patients may select pricier yet highly effective and durable drugs, exemplifying the market positioning of B/F/TAF. With the introduction of innovative antiretroviral therapies and the evolution of China's economic landscape, the HIV treatment environment has gradually been optimized. Consequently, patients may increasingly prefer B/F/TAF despite higher costs, gaining wider acceptance in the evolving HIV treatment landscape.

However, it's crucial to recognize limitations. Firstly, achieving precise control over the clinical trial effectiveness of both interventions is nearly impossible. There are no direct trials establishing efficacy, and the support from network meta-analysis for indirect clinical evidence is insufficient. Secondly, to ensure the smooth progress of our study, individuals discontinuing first-line treatment transitioned entirely to second-line therapy, and those discontinuing second-line moved directly to third-line therapy. Some practical aspects, such as adherence and patient choice, are overlooked in this setup. Lastly, the lack of Chinese research on certain parameters, such as clinical parameters compelled us to adopt foreign parameters for substitution. The dynamic model started in 2015 due to data completeness, using the complete dataset from 2015 to 2019 for model construction and validation. Despite introducing uncertainty in long-term extrapolation, we addressed it with sensitivity analyses in the study.

The model, which incorporates parameters not fully representative of the Chinese context and is predicated on a cohort of adults (≥18) in China, yields results that are specifically applicable to this Chinese patient cohort. If these data become available in the future, our study will be supplemented.

Conclusion

In China, the HIV treatment landscape has improved with innovative antiretroviral therapies. B/F/TAF, despite its higher cost, is increasingly preferred due to its significant effectiveness. Our economic evaluation using both Markov and dynamic models confirms B/F/TAF's superior cost-effectiveness, reducing HIV-related deaths, adverse events, and new infections. The dynamic model, which incorporates transmission dynamics and thus adds complexity and uncertainty compared to the Markov model, enhances the comprehensive assessment of long-term outcomes and public health impact. We strongly advocate for B/F/TAF as the first-line treatment in China's HIV management guidelines.

Abbreviations

B/F/TAF, bictegravir/emtricitabine/tenofovir; DTG/3TC, dolutegravir/lamivudine; MSM, Men who only have sex with men; MIDU, Male: Injection drug-using men who are not MSM; FIDU, Female: Injection drug-using; ADEs, AIDS-defining events; AEs, adverse reactions; QALYs, quality-adjusted life-years; INMB, incremental net monetary benefit,

ICER, incremental cost-effectiveness ratio; LY, life year; WTP, willing to pay; PSA, probability sensitivity analysis; OWSA, one-way sensitivity analysis; RSD, Relative Standard Deviation.

Data Sharing Statement

The datasets generated or analyzed during the current study are available in the following repositories:

1. National Center for AIDS/STD Control and Prevention
   Website: https://ncaids.chinacdc.cn/
2. Menet - China Pharmaceutical Information Database
   Website: https://www.menet.com.cn/
3. China Statistical Yearbook
   Website: http://www.stats.gov.cn/sj/ndsj/.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

All authors declare no competing interests for this work.

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